# Survey Operations Protocol Manual

# Table of Contents

Overview ..... **Error! Bookmark not defined.**
PART 1: Translation Protocol ..... 5
1. Translation Preparation ..... 5
2. Translation Procedures ..... 6
3. Textual Adaptations ..... 6
4. Instrument Preparation ..... 8
Translation instrument pre-testing: ..... 8
5. Field Test Translation Verification and Instrument Review ..... 9
6. Final Instrument Review ..... 9
PART 2: Sampling Protocol ..... 11
1. Overview ..... 11
2. Neighbourhood Sampling Strategy ..... 14
3. School, Workplace and Healthcare Setting Sampling ..... 16
4. Sampling Size Calculations ..... 18
PART 3: Field Test Protocol ..... 19
1. Survey Administration ..... 19
2. Feedback, Data Entry, and Quality Control ..... 20
3. Data Analysis ..... 21
PART 4: Interviewer Training Protocol ..... 22
1. Training Interviewers ..... 22
2. Quality Assurance Checks ..... 23
3. Aggregating Qualitative Data from Interviewers ..... 23
PART 5: Data Collection and Management Protocol ..... 24
1. Overview of Data Collection Tools ..... 24
2. Data Collection Tasks and Responsibilities ..... 25
3. Preparation of the Data Collection Tools ..... 28
4. Data Collection: Surveys ..... 31
5. Data Collection: Physical and Biological Measurements ..... 36
6. Preparation of the Database ..... 44
7. Data Entry and Management ..... 45
APPENDICES ..... **Error! Bookmark not defined.**
APPENDIX A: Document of Suggested Changes ..... 47

APPENDIX B: Sample Mapped Instrument Page ..... 48
APPENDIX C: Site-Specific Estimates of Sample Size ..... 49
APPENDIX D: Kish Household Coversheet and Kish Method Examples ..... 53
APPENDIX E: Field Test Participant Instructions and Feedback Forms ..... 57
APPENDIX F: Interviewer Comment Sheet ..... 59
APPENDIX G: Data Entry Form ..... 60
APPENDIX H: Quality Control Report Form ..... 61
APPENDIX I: Adult Hypotheses ..... 70
APPENDIX J: CIH Indicators Linked to “Core” Adult Surveillance Instruments ..... 72

# OVERVIEW

This manual presents the protocols and methods for the Community Interventions for Health pilot initiative. The manual is organized into the following sections:

1. Translation
    - Translation preparation
    - Translation procedures
    - Textual adaptations
    - Instrument preparation
    - Field Test translation verification and instrument review
    - Final instrument review
2. Sampling
    - Overview
    - Sampling strategies and study methodology
    - Sample size calculations
3. Field testing
4. Data Collection and Management
    - Overview of Data Collection Tools
    - Data Collection Tasks and Responsibilities
    - Preparation of the Data Collection Tools
        - Organising data collection instruments
        - Creating Survey Packages for Each Setting
        - Labelling Surveys
    - Data Collection: Surveys
        - Distribution
        - Administration
    - Data Collection: Physical and Biological Measurements
    - Preparation of the Database
    - Data Entry and Management

# PART 1: Translation Protocol

## 1. Translation Preparation

### Documents:

All instruments must be translated into the site-specific primary language(s). A 'primary language' constitutes any language of the region that is spoken by 10% or more of the population. Instruments to be translated include the following:

- Adult Survey Modules
    - Adult Core
    - Workplace
    - Clinical Practice
    - Cohort
- Youth Survey Modules
    - Youth Core
    - Youth Subset
    - Previous Day Physical Activity Recall (PDPAR)
    - 24-hour food and beverage recall (optional)[1]
- Serving size chart (to be administered with the Adult Core and Youth Core Modules)
- Biometric Measurements Form

### Language:

The primary languages of the intervention and comparison communities should be chosen as the study site languages. Efforts should be made to accommodate all languages routinely used in the intervention and comparison communities; therefore, one study site may need to develop instruments in more than one language. Though different versions may not be needed for different dialects of the same language, translations must be sensitive to word choice as to ensure comprehension across dialects and socioeconomic levels. Similar considerations need to be made for both the intervention community and the comparison community at each study site.

### Translators:

Two translators not involved in the development of the instruments should be selected for instrument translation. These individuals must be fluent in English and the target study site language. The tasks of Translator A and B are outlined below.

[1] This instrument may also be administered to adults in the Neighbourhood Family Cohort Study. The instrument, however, only needs one translation per language as the instruments administered to youth and to adults are identical.

The CIH Pilot study (2008 Field Test) originally prescribed the use of three translators. The original protocol included two translators independently translating all instruments and agreeing on one translation for each instrument. A third translator then was to back-translate each instrument into English and compare it with the original international version. Finally, this third translator was to make suggestions to the site team for improving the final translated instruments.

This process was deemed too labour-intensive and time-consuming; as such, the sites were unable to complete all steps (see the CIH Technical Report (forthcoming) for details on steps completed by each site). The translation procedures expected of CIH sites have been simplified based on this pilot experience and are detailed below.

## 2. Translation Procedures

**Step 1:** Translator A translates each instrument from English into the target language(s) with consideration for diverse dialects, instrument reading level, and adaptations relevant for the study communities (see Section 3 below).

**Step 2:** Translator B translates each of the translated instruments back into English. (This step is called back-translation.)

**Step 3**: For each document, Translator B compares the original English version with the back-translated English version. Translator B notes words or items from this comparison that are unclear, that change the meaning or intention of the original English, or that make the reading level of the document more difficult. Translator B suggests changes based on this comparison. Translator B submits the back-translated documents and a ***Document of Suggested Changes*** to the site study team for review. (see Appendix A for this form)

**Step 4:** Based on the English back-translation and Translator B's suggestions, the site study team makes decisions on the final translated version of the instruments. The site study team may seek input from any of the translators to ensure the best translation.

When translations of specific surveys, questions, or items are already available in a given language, these sections of the instruments do not need to go through Step 1 above. The item or instrument must still go to Translator B for back translation, suggested changes, and incorporation of community language considerations.

## 3. Textual Adaptations

Adaptations should be made to ensure that individual items capture what is intended in survey development. Such adaptations may include the following:

- Metric: measurements must be in local units (eg, kg. vs. lbs.)
- Conceptual: the purpose and meaning of the questions must be considered (eg, equivalent fat content: muffin vs. scone; equivalent rigor of physical activity: cricket vs. baseball)
- Linguistic: words and phrases may be contextual (eg, elevator vs. lift; neighbourhood vs. neighbourhood; vigorous vs. very hard)

Conceptual content may be quite difficult to adapt. For nutrition equivalents, it is important to consider issues such as fat, salt, and nutritional content; translators may use the *Dietary Reference Intakes* report from the Institute of Medicine (2006). For questions related to physical activity, it is important to

provide activities that are equivalent in intensity and energy expenditure. A list of activities that fall in low (0<3), moderate (3-6 METS), or rigorous (>6 METS) activity levels are provided in the Compendium of Physical Activities by Barbara Ainsworth. (See Ainsworth BE. (2002, Jan.) *The Compendium of Physical Activities Tracking Guide. Prevention Research Center, Norman J. Arnold School of Public Health, University of South Carolina. Retrieved [Aug. 26, 2008] from http://prevention.sph.sc.edu/tools/docs/documents_compendium.pdf*)

Specific instructions for adaptations of surveys:

1. Terms in **< >** brackets should be adapted in each country using the appropriate term for your setting (eg, <chips> may be adapted to crisps in the UK). Brackets should be removed in the final instruments.

2. Several items indicate the need for country-specific examples. Country-specific examples should be entered in locations that are highlighted and indicate the need for examples in capital letters. (ie, [PROVIDE COUNTRY-SPECIFIC EXAMPLES]) In these locations, please insert the most common examples for your setting. Other examples provided throughout the surveys should not be modified without permission.

All adaptations will be noted by the site study team in a ***Mapped Instrument***. Information on the different terms used across countries will be necessary when conducting cross-country analyses.

> For the CIH Pilot Study (2008 Field Test), all country sites used an Adaptation Table to note adaptations and country-specific examples. The *Mapped Instrument* was later substituted for the Adaptation Tables, as it may be used for both translation and adaptation purposes, as well as for data entry, management, and analysis purposes. The CIH *Mapped Instrument* is adapted from the WHO STEPS Mapped Instruments.

## Instructions for Completing Mapped Instruments

The CIH ***Mapped Instrument templates*** present each CIH survey module (Adult Module, Adult Workplace Module, Clinical Practice Module, Youth Module, Youth Subset Module, PDPAR) in its International (generic) version in a format to assist with data entry, management, and analysis. The purpose of these documents is to note any country adaptations to the surveys and to map these adaptations to the generic survey modules. This will make data management and analysis easier and more straightforward. The ***Mapped Instruments*** also will be useful for data entry training and data entry itself, as each module is mapped to a variable and coding for response options.

**Figure 1: Sample Mapped Instrument rows**

| General Health | | | Response Choices | | Code (variable name) | |
|---|---|---|---|---|---|---|
| **CIH Q No.** | **Site Q No.** | **CIH Generic Question** | **CIH Generic** | **Site Specific** | **CIH Generic** | **Site Specific** |
| 1 | | How tall are you without your shoes on? | Numeric (meters) (should be a positive real number)<br>Missing [0] | | Q1Z1 | |
| 2 | | How much do you weight without your shoes on? | Numeric (kilograms) (should be a positive real number)<br>Missing [0] | | Q2Z1 | |

Each site is responsible for completing the ***Mapped Instrument*** cover page (not shown) and 3 columns throughout the document (Site Q No., Site Specific Response Choices, and Site Specific Code (variable name). These columns are highlighted in blue in Figure 1 above. Additionally, if any changes have been made to the questions in addition to response options, please note this using red font in the CIH Generic Question column (highlighted in orange in Figure 1), directly under the generic questions.

The ***Mapped Instrument templates*** provided by the Evaluation Team match the International (generic) surveys; country-specific response options are included. **It is very important to make sure to delete these country-specific response options if they are not utilised, or to adapt them as necessary.** Also, if a country site has added additional response options to a question, or has added additional questions, these modifications should be done in the ***Mapped Instrument***.

See Appendix B for a full sample template page; the full templates are available upon request from the Evaluation Team.

## 4. Instrument Preparation

Instructions and questions must appear in the same order as the original English version of the instrument. Document formats should also remain as close to the original English versions as possible. Variations due to textual variations in the study site language(s) such as right-to-left versus left-to-right print are acceptable. These variations may also be noted in the ***CIH Mapped Instrument Template***.

### Translation instrument pre-testing:

The final translated version of each instrument should be pre-tested prior to sending to the Evaluation Team for verification.

**Step 1**: Two age-appropriate individuals from diverse backgrounds are selected to complete each survey. (Diversity by characteristics such as class, socioeconomic status, gender, and age should be considered.)

**Step 2:** A study member meets with each individual as they complete the surveys. (This meeting may be in a focus group or one-on-one format). The study member should inquire about individual questions and items after each section is completed (eg, after an individual completes the demographics section, review each question with them). This inquiry should consist of questions to assess the purpose, clarity, and completeness of each item.

**Step 3:** Translations of each instrument should be updated based on pre-testing feedback. (Any feedback not related to translation should be noted in a separate document and sent to the Evaluation Team. Changes beyond translation of items such as changes to the content of the item should not be made to individual items at this time. This document will be reviewed by the Evaluation Team and in consultation with the site teams during the survey revision process.)

**Step 4:** Field-test quality instruments should be prepared.

**Step 5:** All field-test quality instruments, the document noting pre-test feedback, and ***CIH Mapped Instruments*** should be sent to the Evaluation Team at MATRIX Public Health Solutions, Inc. for verification and review.

## 5. Field Test Translation Verification and Instrument Review

The Evaluation Team will work with consultants to review all adaptations and translations to ensure that the intent of each question is maintained and that the surveys are similar across sites. The Evaluation Team will submit to each country site team an ***Instrument Review Document*** listing suggested and necessary changes to be made to each instrument prior to field testing. Sites are responsible for incorporating all changes into the translated versions of the instruments. This may require translation of new items and item parts.

After staff at each site implements the revisions noted by the Evaluation Team in this verification and review process, the final instruments should be prepared at each site for the Field Test.

## 6. Final Instrument Review

The Evaluation Team, in consultation with the site teams will revise translated, country-specific instruments based on the results of the Field Test. No instruments are finalised and no baseline surveys should be administered prior to the final translation verification process has been completed.

The final translation steps are as follows:

**Step 1:** Items requiring improved translations or clarification are retranslated by site translators.

> During the 2008 Pilot Study, the translation process involved several rounds of revisions of the international versions of the surveys. For this reason, sites had to ensure that all changes made to the international versions of the surveys were reflected in their translated versions. Beyond the pilot study, all sites must discuss any changes not in line with the international version of the survey with the Evaluation Team to ensure data comparability.

**Step 2:** Final baseline-ready instruments are created.

**Step 3:** Baseline-ready instruments are submitted to the Evaluation Team for instrument review. **Step 4:** The Evaluation Team works with consultants to review the final translation of the instruments, comparing the final translated instruments to the international versions. The consultants note any necessary changes to be made to the final translated instruments for the baseline assessment.

**Step 5:** Site teams update translations based on feedback.

**Step 6**: Mapped Instruments are finalised and sent to the Evaluation Team.

After **Step 6** has been completed, the instruments are ready for baseline data collection.

**References:**

O'Connor, K.M., & Malak, B. (2000). Translation and cultural adaptation of the TIMSS instruments. In M.O. Martin, K.D. Gregory, & S.E. Stemler (Eds.). *TIMSS 1999 technical report* (pp. 89-100). Chestnut Hill, MA: Boston College

Cultural Adaptation Translation and back translate section, International Physical Activity Questionnaire. Retrieved [Feb 10, 2004] from <http://www.ipaq.ki.se/IPAQ.asp?mnu_sel=FFA&pg_sel=>

# PART 2: Sampling Protocol

## 1. Overview

Sampling frames used in each sample selection should be comprehensive and well-documented at each site by including all individuals or venues in the intervention and control sites. Simple random sampling strategies will be employed. Particular attention will be directed towards ensuring full representation by age, gender, and ethnicity when the sampling frame is chosen. If there is a concern for under-representation of certain subgroups, additional stratification may be conducted but sample size will need to be increased[2].

In cases of non-response or refusal to participate, as much as possible, demographic information about the individual/venue should be recorded. In order to adjust for potential non-response and refusal, the sample size in each setting will be increased by 20% (therefore if the sample size is to be 1,000 in the neighbourhood cross-sectional study, 1,200 households should be sampled).

The Evaluation Team and sampling expert will work with each site when conducting sampling. The sampling frame and strategy will be reviewed with each site independently to ensure common sampling methods are employed across sites while adjusting for site-specific issues.

It is critical that sampling be conducted similarly in intervention and control communities. The control site will require the same number of surveys to be obtained as in the intervention site, based on the fact that they should be similar in baseline prevalence of the 3 risk factors. In addition, the procedures used in the baseline sample selection should be replicated for the follow-up sample selection.

Developing and developed countries will be treated differently due to the increased availability of data in developed countries on the three CIH risk factors (for example, children in schools)[3]. Table 1a reflects the developing country sampling guideline; this must then be adapted to the prevalence of the risk factors in individual sites. In Table 1b, the sampling for the UK pilot site is provided as an example of the size reductions that will be common for developed country sites due to the availability of data for comparison purposes.

[2] Contact the Evaluation Team if your sample will use stratification in order to assess/report the adjusted sample size required.
[3] An additional consideration for developed country sample size has been the higher cost of labour associated with data collection as well as interventions.

**TABLE 1a: ORIGINAL GUIDELINE FOR DEVELOPING COUNTRY SAMPLING: Total Number of Participants[4] [5]**

| Country/ Community | Survey Sample per Developing Country Site* | | | | |
|---|---|---|---|---|---|
| | Neighbour-hood | School Children | Workplaces (including industry, health centres, & schools) | Health Care Providers (Doctors and nurses) | TOTAL |
| **Intervention site** | 1,000 | 2,000 | 2,700 (1,000, 1,000, 700) | 400 | 6,100 |
| **Control site** | 1,000 | 2,000 | 2,700 (1,000, 1,000, 700) | 400 | 6,100 |
| **SAMPLE AGGREGATE** | 2,000 | 4,000 | 5,400 | 800 | 12,200 |

[4] Twenty percent (20%) should be added to account for non-response and refusal rate for a total of 14,640.

[5] With adjustment in sample size made to reflect the current prevalence for each site

**TABLE 1b: EXAMPLE OF DEVELOPED COUNTRY SAMPLING - Total Number of Participants**[6] [7]

| Country/ Community | Survey Sample per Developed Country Site | | | | |
|---|---|---|---|---|---|
| | **Neighbour-hood** | **School Children** | **Workplaces (including industry, health centres, & schools)** | **Health Care Providers (Doctors and nurses)** | **TOTAL** |
| **Intervention site** | 1,400 | 1,500 | 1,400 (1,000, 200, 200) | 400 | 4,700 |
| **Control site** | 1,400 | 0[8] | 1,400 (700, 700, 0) | 400 | 3,200 |
| **SAMPLE AGGREGATE** | 2,800 | 1,500 | 2,800 | 800 | 7,900 |

Sample size calculations and estimates (to be done by the Evaluation Team using prevalence data provided by sites; see Appendix C for site-specific estimates to date) follow an exhaustive review of prevalence rates for the three primary risk factors (tobacco use, unhealthy diet, and physical inactivity) and are based on the following assumptions:

- significance level ($\alpha = 0.05$);
- power of test (two levels: $\beta = 0.10$ and $\beta = 0.20$);
- two-sided test of hypothesis;
- sample selection by simple random procedure;
- independent samples for each survey;
- 6% change in risk factor levels [tobacco use (as defined by current use), unhealthy diet (as defined by eating fewer than five servings of fruits and vegetables daily), and physical inactivity (as defined by IPAQ[9]); and
- current prevalence risk factor levels (adult and child, by gender where available).

[6] Illustrative of reductions in sub-samples that are then supplemented with existing data

[7] 20% should be added to account for non-response and refusal rate for a total of 9,480.

[8] Replaced by comparable data from local, regional or national surveys; sites will assist in the identification and procurement of comparison data

[9] IPAQ inactive is defined as "not meeting any of the following three criteria: 3 or more days of vigorous activity of at least 20 minutes per day OR 5 or more days of moderate-intensity activity or walking of at least 30 minutes per day OR 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min/week.

## 2. Neighbourhood Sampling Strategy

All CIH sites will use the same sampling strategy – stratified random sampling – for the community sample. This common strategy will allow for the aggregation of data across sites. Stratification is helpful when there is a lot of variability in a relevant variable within the population being studied. It produces more accurate estimates than random sampling. Where SES data are not available, are not heterogeneous, or not relevant to the hypotheses under study, simple random sampling will be used.

Different sampling strategies at the community neighbourhood level would negatively impact the aggregation of the data and, in its most extreme, allow only meta-analyses of the data rather than cross-country comparisons. All sampling methods have their own set of assumptions. Both sample size and sampling framework (in terms of the geographic distribution of potential participants over the entire intervention and control areas) are impacted by the cost and burden that can be assumed by the site team. Random sampling generally results in greater costs than clustered sampling. However, the increased sample size needed when conducting cluster sampling would likely negate its financial benefits.

Demographic variables of interest for CIH are gender, socioeconomic status (SES), and age. SES will be gauged through a variety of formal and informal measures (e.g., roof types, income from census). The informal measure of SES will result in community measures rather than that of individual households. The fact that some countries have information on SES only for relatively large geographic areas but not at the cluster level (administrative unit) rules out stratified cluster sampling (clusters cannot be stratified with little information on SES). It is preferable for sites to use 3-4 SES strata (discussion should take place with the Evaluation Team for sites wanting more or less strata). Therefore, ***stratified random sampling*** by SES (proportional to size, with over-sampling where necessary for small age subgroups) will be used for the CIH Project. If the site is interested in generated estimates for each SES strata individually (rather than using stratification solely for the purposes of increasing efficiency), an equal number of participants from each strata should be recruited into the sample (This is called disproportionate sampling and sample size calculations must be conducted to determine the number per stratum).

Age and gender stratification will be used to assure 100 participants per age-gender cell (quota sampling). This age/gender enumeration is necessary in order to generate surveillance data and, when statistical power is sufficient, to allow assessment by strata. The use of quota sampling is strengthened by the integration of the Kish method for selecting persons from households. Following the use of the Kish method to ascertain participants across all age and gender strata, cells will be filled using oversampling to reach their quota.

**Table 2: Age and gender strata**

| Age Strata | Male | Female |
|---|---|---|
| 18-24 | 100 | 100 |
| 25-34 | 100 | 100 |
| 35-44 | 100 | 100 |
| 44-54 | 100 | 100 |
| 54-64 | 100 | 100 |

For gender and age stratification (see Table 2 for age-gender cell sizes), the following methods are required:

- Where *age and gender are available for all adult household members*, stratification should be conducted on these two variables and a random sample *listing generated for the interviewers* with one adult selected from each household using the Kish Method. The Kish Method outlined in the WHO Steps Manual should be utilised (STEPs Manual Section 2 Part 2). The Kish Method requires the age and gender of each adult (aged 18-64 for CIH) be used to assign them a rank. Males are first assigned a rank in order of decreasing age and then the same is done for females. For the purposes of utilising the Kish Method with electronic listings of households and their members, the method needs to parallel that of the Kish Household Coversheet (Appendix D). An algorithm must be created to select the correct person based on the two factors which are combined in the Kish Selection Table: the last digit of the household number and the number of eligible persons in the household. **If over-sampling is required to reach the quota for a specific age/gender group, the "Kish Method of over-sampling" should NOT be used.** Rather, every third household should be examined for a person in the over-sampled group. If present in that household, that person should be selected as the only adult selected from the household. If there are multiple persons in the over-sampled group within a household selected for over-sampling, select one of those persons at random.
- For those *sites which do not have age and gender information on adults in the household*, sampling for age and gender will be conducted during the *recruitment/interview phase* of the project through the Kish Method (STEPs manual Section 2 Part 2). For each household, a Kish Household Coversheet will be completed. The Kish Method requires the age and gender of each adult (aged 18-64 for CIH) be used to assign them a rank. Males are first assigned a rank in order of decreasing age and then the same is done for females. Using the Kish Selection Table, the last digit of the household number and the number of eligible persons in the household are combined to indicate which person should be selected in that household. **If over-sampling is required to reach the quota for a specific age/gender group, the "Kish Method of over-sampling" should NOT be used.** Rather, every third household should be examined for a person in the over-sampled group. If present in that household, that person should be selected as the only adult selected from the household. If there are multiple persons in the over-sampled group within a household selected for over-sampling, select one of those persons at random.

- The age/gender cell number is 100 per cell. **Administrative oversight of recruitment should review filling of age/gender cells at each 10% increment in the sample in order to be able to integrate over-sampling if necessary during the standard data collection period (rather than have to extend data collection for over-sampling).** Use of the over-sampling procedure should guarantee reaching the required number of those being over-sampled. Discussion with the evaluation team should take place in situations where it does not appear feasible to fill specific age-gender cells. This age/gender enumeration is necessary in order to generate surveillance data and, ***when statistical power is sufficient, to allow assessment by strata.***

Please note: For the generation of baseline surveillance data, the intervention and comparison communities data collected at baseline will be combined and weighted. This will allow for age/gender group estimates of risk factor prevalence.

Country-specific sample size estimates are to be calculated based on their prevalence of risk factors, by gender (where possible) and separately for adults and children (where possible). Country-specific sample tables are included in the appendices. In situations where gender-specific data are not available, the overall sample size may preclude meaningful gender-specific analysis. ***If sites intend to examine gender-specific effects and current gender-specific data reveal the required sample***

***size to be greater than the international guideline for sample size, country-specific sample sizes need to be increased appropriately.*** Similarly, where child data are not available, we cannot currently ascertain if the established sample size of 2,000 children has sufficient power (overall or by gender) for the examination of the specific risk factors.

Lastly, it is important to note that the examination of particular risk factors is precluded in specific subgroups where needed sample sizes are much higher than the feasible sample sizes given the nature of this pilot study and cost-burden. Gender-specific unhealthy diet change in India is a good example of this situation. For the examination of gender-specific diet changes, in order to have 80% power to detect a 6% difference in males and in females, a total of 2,150 persons are needed (1,050 males and 1,095 females). For gender-specific tobacco use in China, a total of 1,400 adults would be needed for 80% power. Due to cost-burden and nature of the pilot study, the number of adults in the community sample was capped at 1,000 persons for intervention and 1,000 for control communities for developing country sites[10]. Adults in the workplace sample may be combined with the adult community sample to increase sample size for the Adult Module, but this would preclude use as surveillance data as the workplace samples are convenience samples.

In addition to statistical power for a given sample size, the issue of the precision of the generated estimates must be understood by each site. Given the variability in the prevalence of the many risk factors, a given sample size provides a given confidence interval for each estimate (range of population value with a given amount of certainty).

The international guideline for sample size for each site is 12,200 individuals (6,100 intervention site & 6,100 control site) for developing countries, and 7,900 individuals (4,700 intervention site & 3,200 control site) for developed countries. In order to obtain this sample, over-sampling by 20% is the standard.

***Individual sites must be clear about the ramifications of the general sample size in terms of the data analyses and research conclusions that will be "sufficiently powered" for their site.***

See Appendix C for country-specific estimates of sample size and estimate precision at 80% power for gender-specific estimates. Confidence intervals (precision estimates) are generally around 3.0, with some smaller intervals estimated for China.

## 3. School, Workplace and Healthcare Setting Sampling

In addition to the sampling of the community neighbourhoods, strategies for use in schools, workplaces and health care settings have been developed. As countries/sites have different structures and considerations for their schools, workplaces, and health care settings, each site will discuss sampling with the Evaluation Team to reach agreement on specifics regarding sampling.

Table 3 on the next page presents the overall study methodology including samples by setting and method of survey administration.

[10] For developed country sites, higher costs and a greater level of population data on chronic disease and risk factors led to a decision to decrease the comparison samples at these sites and raise the community sample (in Leicester to 1,400 adults in intervention and 1,400 in control).

## TABLE 3: SAMPLING AND DATA COLLECTION METHODOLOGY

| | Sampling | Sample Size (guidelines based on developing countries)* | Surveys | Survey Administ-ration Method | Biomarkers |
|---|---|---|---|---|---|
| **Neighbourhood** | Cross-sectional of all households; simple or stratified random sample | 1,000 households | Adult Core Module | Face-to-face interview (at home) | Sites encouraged, but not required to collect |
| **Neighbourhood Family Cohort** | Randomly selected from neighbourhood cross-sectional | 200 adults[11] | Adult Core, Cohort, 24-hour food and beverage recall (optional) | Face-to-face interview (at home) | All biomarkers: height, weight, hip and waist circumference, blood pressure, heart rate, skin-folds (optional)<br>rapid test for fasting glucose, LDL, HDL, total cholesterol, triglycerides |
| **School Children** | 20 schools<br>at least 2 classes in each grade for which students in the grade are predominately 12- and 14-yrs-old | 2,000 students | Youth Core | Self-administered | Physical biomarkers: height, weight, hip and waist circumference, blood pressure (optional), heart rate, skin-folds (optional) |
| **School children:**<br>subset | Random subset of classes in child sample (50% from each of the two grades) | 200 students with assistance of a parent/adult | Youth Core, Youth Subset, PDPAR, 24-hour food and beverage recall (optional) | Self-administered | See above (school children) |
| **Workplaces:** industry | All workers;<br>Exception: Random selection of workers in intervention workplaces where there is much larger workforce than needed to meet sample size requirements | 1,000 adults | Adult Core, Workplace Module | Self-administered | All biomarkers: height, weight, hip and waist circumference, blood pressure, heart rate, skin-folds (optional)<br>rapid test for fasting glucose, LDL, HDL, total cholesterol, triglycerides |
| **Workplaces:** schools | All administrators, teachers and support staff or a random sample proportionate to size if larger schools are involved | 700-1,000 school staff | Adult Core, Workplace Module | Self-administered | Sites encouraged, but not required to collect |
| **Workplaces:** hospitals | All non-medical workers;<br>Exception A random sample of all non-medical professionals from participating health care centres with sample proportionate to size where there is much larger workforce than needed to meet sample size requirements | 1,000 health centre staff | Adult Core, Workplace Module | Self-administered | Sites encouraged, but not required to collect |

[11] Optional component of Neighbourhood Family Cohort study: Collecting the Youth Core Module and physical biomarkers from a random child (aged >11) within a selected household.

| | Sampling | Sample Size (guidelines based on developing countries)* | Surveys | Survey Administ-ration Method | Biomarkers |
|---|---|---|---|---|---|
| Health Care Professionals | All medical professionals; Exception: A random sample of all medical professionals from participating health care centres with sample proportionate to size where there is much larger workforce than needed to meet sample size requirements | 400 health care professionals (ie, doctors and nurses) | Clinical Practice Module | Self-administered | None |

* Most samples will be adjusted for 20% non-response and refusal rate.

## 4. Sample Size Calculations

As presented in Tables 1a and 1b above, the overall sample size for each developing country site is 12,200 individuals (6,100 intervention site & 6,100 control site) and for each developed country site is 7,900 individuals (4,700 intervention site & 3,200 control site). The final sample size determined meets or exceeds 80% power. Calculations were conducted and presented below in order to ensure appropriate statistical power to detect differences, particularly given the fact that several hypotheses are being tested. For each risk factor, site specific literature was reviewed to determine current prevalence rates for the risk factors (site specific; adult and child, by gender; these are presented as footnotes in the table). For many of the risk factors sufficient information was not available, particularly for children.

As previously mentioned, sample size calculations were based on the following: 1) a significance level of ($\alpha = 0.05$); 2) power of test (two levels: $\beta$ =0.20 and 0.10); 3) two-sided test of hypothesis; 4) sample selection by simple random sampling 4) independent samples at each survey (panel study); and 5) 6% change in risk factor levels (smoking/tobacco use, unhealthy diet, and physical inactivity). These site-specific sample size calculations can be viewed in Appendix C.

# PART 3: Field Test Protocol

The CIH Field Test has three primary purposes:

- to trial the instruments for length of time, ease of administration, readability, and applicability to each country;
- to trial the different methods of administration (ie, paper-and-pencil and mobile device); and
- to assess the data entry, retrieval, and analysis processes.

The CIH Pilot Study Field Test, which took place from May to July 2008 in China, India, Mexico, and the UK, also served the purpose of generating respondent- and site-team-based revisions to the CIH baseline surveys (international versions). The baseline Pilot Study surveys have since been finalised. Therefore, all subsequent Field Tests should be conducted individually by sites and should not result in any changes in the main CIH surveys. Country-specific adaptations and additions, however, are permitted and encouraged.

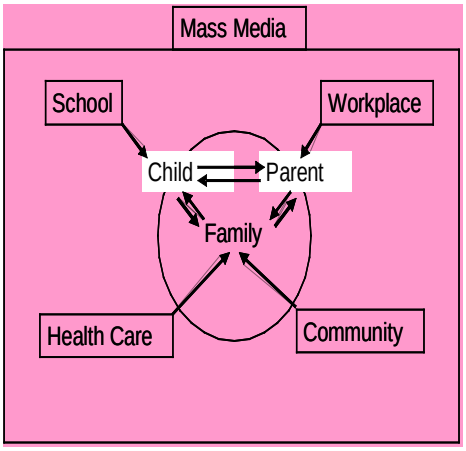



**Figure 2: Comprehensive Community Intervention**

## 1. Survey Administration

A convenience sample should be selected to field test each module. Forty adults should be selected to take the Adult Module and Workplace Module together – 20 administered by paper-and-pencil and 20 by mobile device if mobile devices are being used. Another 20 adults should be selected to field test the Adult Module and the Cohort Module together (the surveys to be administered ultimately to the Family Cohort). An additional 20 'health care professionals' should be selected to field test the Clinical Practice Module.

A convenience sample of 20 youths should be selected to complete the Youth Module, Youth Subset Module, PDPAR and optional 24-hour food and beverage recall with assistance from a parent/adult.

See Table 4 for details on these Field Test survey administration methods.

> The CIH Pilot study (May 2008 Field Test) originally required sites to field test data collection using PDAs. At the time that the Field Test was conducted, the Pilot Study sites were not yet ready or equipped to administer surveys using these mobile devices. Additionally, at the time of the Field Test, a 24-hour food and beverage recall was to be included, but was since dropped to reduce the burden in data collection and increase study feasibility.
>
> All sites field tested the surveys to 80 individuals (see the CIH Technical Report (forthcoming) for details on steps completed by each site). The field test procedures expected of CIH sites have been simplified based on this pilot experience and are detailed below.

*

**Table 4: Field test survey administration**

| PARTICIPANTS REPRESENTED | SURVEY(S) ADMINISTERED | METHOD OF ADMINISTRATION | |
|---|---|---|---|
| | | Paper-and-pencil | Interviewed Mobile device* |
| Neighbourhood Adults and Workplace Adults | Adult Module and Workplace Module | 20 | 20 |
| Family Cohort Adults | Adult Module and Cohort Module and optional 24-hour food and beverage recall | | 20 |
| School Children and Subset of School Children | Youth Subset Module, PDPAR, and optional 24-hour food and beverage recall (completed with assistance from parent/adult) | 20 | |
| Health Care Workers | Clinical Practice Module | 20 | |

*****For sites not using mobile devices, 20 adults will complete the Workplace instruments (Adult Module and Workplace Module), and 20 adults will complete the Neighbourhood Family Cohort instruments (Adult Module and Cohort Module) recorded by interviewer using paper-and-pencil. The field testing of other instruments should be completed as stated above.

## 2. Feedback, Data Entry, and Quality Control

Generating useful feedback based upon the Field Test is vital. To obtain systematic and useful feedback for any CIH site conducting a Field Test, and to ensure continual improvement to the CIH programme, the following feedback documents should be used for all Field Tests:

- Field Test Participant Instructions and Feedback Forms
- Interviewer Comment Sheet
- Data Entry Form
- Quality Control Report Form

These documents are included in Appendix E-H at the end of this manual and are described in the following sections.

### Survey Feedback

> For the CIH Pilot Study Field Test in May 2008, a *Field Test Interviewer Comment Sheet* and a *Field Test Data Entry Form* were provided for Field Test feedback. While working with sites during the Field Test, however, additional feedback documents were created that eased the Field Test process and enabled sites to supply very helpful and constructive feedback. These forms are noted above and provided in this updated protocol in the Appendix (*Field Test Participant Feedback Instructions* and *Feedback Documents*).

A separate sheet should be provided for the interviewer to note any adjustments or additional changes that are required in order to clarify questions for respondent during the interview.

Focus groups should be conducted to obtain feedback on participants' experiences with the instruments. A focus group of 8 – 12 individuals should be conducted for each one of the six groups

noted in Table 4. The focus groups should consist of questions to assess the purpose, clarity, and completeness of items as well as length of time for completion, ease of administration, and readability overall. The ***Field Test Participant Instructions and Feedback Forms*** should be utilised during these focus groups and all participant feedback, both positive and negative, should be noted. The ***Interviewer Comment Sheet*** should also be used for documenting all comments and suggestions made by the interviewer/proctor. Incentives may be provided for participation in the Field Test.

**Data Entry and Quality Control**

Where applicable, the 40 surveys administered using mobile devices should be uploaded directly to the online survey database (Vovici Survey Software at http://efm.matrixphcsurveys.com).

The remaining surveys should be entered using the same method as the one that will be used for the baseline and follow-up data collection (scanned or data-entry by hand).

When data entry is conducted by hand, a 20% quality control check is expected. From each set of survey instruments, 20% should be randomly selected by a second party and re-entered. The number of discrepant entries should be noted on the ***Data Entry Form***. An overall ***Quality Control Report Form*** should be completed by the Field Test administrator.

Once all surveys have been entered into the survey database, each site should notify the Evaluation Team.

## 3. Data Analysis

Each site is responsible for summarising all interviewer notes from the ***Interviewer Comment Sheets*** and sending comments to the Evaluation Team, who will review the sheets and incorporate the feedback as appropriate. Review of interviewer notes will result in qualitative findings including but not limited to: questions that required additional clarification, questions where participants showed reluctance to answer, levels of concentration throughout the interview.

In additional to this qualitative data, quantitative data analysis will be performed on a very basic level. Using the Field Test data provided by the country site, comparison testing should be made between the two different administration methods. Individual item responses (distribution of response categories including refused or don't know) and item completion also should be assessed. Analyses of completion time should include the calculation of mean, median, and range of completion times for each method. The Evaluation Team is responsible for this data analysis.

# PART 4: Interviewer Training Protocol

Interviewers need to be trained for the collection of data from surveys administered via interviews. For the CIH Pilot Study, this included only the Neighbourhood Adult and Neighbourhood Family Cohort sample; for future CIH sites, this may include other modules as well, depending on individual sites' preferences.

## 1. Training Interviewers

The Site Team, in collaboration and consultation with the Evaluation Team, is responsible for hiring and training field interviewers to administer the surveys. At least 8 interviewers at each site should be hired and trained. These interviewers must be reflective of the target community, and must be able to read and write fluently in the dialects of the target communities. Please note: Due to issues of confidentiality and participant comfort, it is advisable that interviewers not conduct interviews in their own neighbourhoods but rather be assigned to alternate areas (intervention and control).

We recommend that sites base their interviewer training sessions and guides on the WHO STEPS Surveillance Manual Part 3 Section 1 which can be found at http://www.who.int/chp/steps/Part3.pdf. The STEPS Surveillance Manual provides training modules, as well as training tips to supervisors and interviewers. The training and practical guides have been designed for data collection and management supervisors to train their staff in those areas.

The training for the lay interviewers should occur over a 2-day period and incorporate components of the WHO STEPS Surveillance Interviewer Protocol, and should include training on the following key areas:

- Rationale, purpose and organisation of the CIH programme and modules
- How to be part of a data collection team
- Obtaining informed consent
- Interviewing participants, including:
    - Behaviour and tact (respecting confidentiality, respecting participants time, friendly disposition, body language, pace of interview, patience, acceptance, appreciation), asking questions (issues relating to chronic diseases and their risk factors, right or wrong answers, biased answers, reading all options, reading questions, making assumptions), providing clarification, when and how to probe further, interruptions, how to handle refusals, and language issues
- Approaching households (including safety issues)
- Using the survey device (computer or PDA) to complete surveys (if applicable)
- Saving, storing and sending electronic data (if applicable)

The role of the interviewer is to administer the surveys successfully to participants, and to assist them in understanding survey questions and response options wherever necessary. To provide useful feedback on the survey modules and their administration, each interviewer will be responsible for completing ***Interviewer Comment Sheets*** (see Appendix F). After completing an interview, the interviewer should note all questions asked by the participant during survey administration, including items or words that need clarification. Interviewers should also note if a participant is evidencing difficulty with understanding or completing an item as well. Any comments that may help to improve the

instruments would be helpful. Interviewers may note any additional comments in the space provided on the ***Interviewer Comment Sheet***.

## 2. Quality Assurance Checks

The Field Coordinator should have a list of each interviewer's interview list, including locations of homes to visit on given days. The Field Coordinator will accompany each interviewer to at least 5 full interviews. A quality assurance visit should be scheduled within the first 10 interviews conducted by each interviewer. Ideally, the interviewer should not be told until the day of the quality assurance check that they will be joined by the Field Coordinator. Any divergence from the interview protocol should be noted on the ***Quality Control Report Form*** (see Appendix H). Additionally, interviewers should be informed of proper procedures to improve the quality of future interviews. All quality assurance discussions should be held AFTER the interview is completed and the interviewer has left the household. For each interviewer, at least 5 quality assurance checks should be conducted by the Field Coordinator during baseline data collection. These checks should be spaced throughout the data collection period though interviewers who are not in adherence with protocol procedures should receive additional support in the beginning of the data collection process.

## 3. Aggregating Qualitative Data from Interviewers

The Field Coordinator should collect all ***Interviewer Comment Sheets*** and summarise the findings. Interviewers should submit their comment sheets after the first 5 interviews have been conducted. The Field Coordinator should then review all ***Interviewer Comment Sheets*** to assess any recurring issues. Those issues should be discussed with the Evaluation Team and measures taken to correct any procedural or survey-specific issue in a timely manner.

The Evaluation Team will collect these ***Quality Control Report Forms*** at the end of baseline and follow-up data collection periods.

# PART 5: Data Collection and Management Protocol

This section contains the following sections describing the data collection, entry and management processes:

1. Overview of Data Collection Tools
2. Data Collection Tasks and Responsibilities
3. Preparation of the Data Collection Tools
    a. Organising data collection instruments
    b. Creating Survey Packages for Each Setting
    c. Labelling Surveys
4. Data Collection: Surveys
    a. Distribution
    b. Administration
5. Data Collection: Physical and Biological Measurements
6. Preparation of the Database
7. Data Entry and Management

## 1. Overview of Data Collection Tools

### Survey Modules

The CIH Survey Modules were developed, reviewed, and finalised by the core CIH team, represented by the CIH Pilot Study sites in China, India, Israel, Mexico, Tunisia, and the UK; the Oxford Health Alliance; external consultants; and an Expert Panel and Advisory Board. (Refer to Page 5 for a list of individuals involved.) The intensive 2-year development process included a thorough review of global studies addressing knowledge of, attitudes towards and beliefs on the three risk factors for chronic disease – unhealthy diet, physical inactivity, and tobacco use – and has resulted in 6 CORE survey modules to be administered in the community, in schools, in workplaces and in health centres (all settings in which CIH interventions will occur).

All CIH Pilot Study sites are required to use, at a minimum, all survey modules; however the modules were developed with the goal of expansion and sustainability in mind. A list of the survey modules and the anticipated strategy for distribution and collection of each are presented below.

Separate modules have been developed to be administered to adults and children (youth). Surveys include:

- Adult Survey Modules
    - Adult Core
    - Cohort
    - Workplace
    - Clinical Practice
    - 24-hour food and beverage recall (optional)

- Youth Survey Modules
    - Youth Core
    - Youth Subset
    - Previous Day Physical Activity Recall (PDPAR) (completed by youth with assistance from parent/adult)
    - 24-hour food and beverage recall (optional, completed by child with assistance from parent/adult)

These survey modules correspond to the four different settings of interest for CIH: neighbourhoods (communities), schools, workplaces, and health care settings. Note that CIH focuses on adults as community members from neighbourhoods as well as adults as workers based in schools, industry, and health care settings. Youth will be surveyed from schools, and information about the habits of youth residing with the adults who complete the Cohort Module will also be collected (separate from the school sample).

### Physical and Biological Measures

In addition to survey modules, a sub-set of individuals will participate in a Biometric Study. The basic Biometric Study includes *height, weight, hip and waist circumference, blood pressure, heart rate, and skin-folds*. In-depth biometric measures include: *rapid test for blood glucose, LDL, HDL, total cholesterol, and triglycerides.*

Adults from the Neighbourhood Family Cohort and all sampled adults from industry will contribute the basic and in-depth biometric measures. All selected children from schools will provide the basic biometric measures, specifically, *height, weight, hip and waist circumference, blood pressure and heart rate (skin-fold measurements are optional)*.

## 2. Data Collection Tasks and Responsibilities

### Tasks and Responsibilities of Site Teams and the Evaluation Team

Each Country Site Team will be responsible for ensuring proper study operations, survey administration, and biometric data collection. Table 5 below summarises the tasks and responsibilities of each Country Site Team and the Evaluation Team for data collection.

**Table 5: Tasks and Responsibilities for Data Collection**

| Country Site Team | Evaluation Team |
|---|---|
| **STEP 1: Develop the sampling frame** | |
| **Obtain demographic information and develop the sampling frame**<br>• Obtain maps of intervention and control areas, including any available GIS maps.<br>• Develop sampling frames.<br>• Collect demographic information from the intervention and control communities, including percent male/female, percent <18 and in 10-year age ranges for 18+ (or if 10 year strata not available, use of finest available strata) and socio-economic levels. If SES data is not available, the Site Team should consult with the Evaluation Team.<br>• Collect demographic information from the intervention and control workplace(s), including percent male/female, percent in given age ranges (10 year strata for 18+) and socio-economic levels (proxy - job type and/or work status).<br>• Send maps, sampling frames, and demographic information to Evaluation Team. | **Guide development of the sampling frame**<br>• Provide each Site Team the Sampling Protocol.<br>• Review the maps, sampling frames and demographic information provided by each Site Team to ensure that they comply with study guidelines for cross-country comparability. |
| **STEP 2: Finalise survey modules** | |
| • Translate and adapt modules (refer to the Translation Protocol).<br>• Conduct Field Test for all modules (refer to the Field Test Protocol).<br>• Complete Mapped Instrument documents for all modules and send to Evaluation Team.<br>• Create and organise survey packages for each setting where surveys will be administered (neighbourhoods, schools, workplaces, health centres).<br>• Ensure survey modules are correctly labelled and create quality assurance measures to ensure all survey data will be correctly linked with data from biometric study.<br>• Verify that all surveys collected have signed consent forms (or passive consent for the Youth Module). | • Develop CIH Survey Modules (international versions) and Mapped Instrument templates and provide them to each Site Team.<br>• Verify correct translation and adaptation of country-specific survey modules with translators and send feedback to the Site Team (refer to the Translation Protocol). |
| **STEP 3: Prepare and create data entry environment** | |
| • Modify and adapt SPSS data entry templates and Mapped Instruments provided by the Evaluation Team.<br>• Set up quality assurance measures to facilitate accurate data entry.<br>• Train individuals for data entry. | • Create and provide each Site Team with SPSS data entry templates corresponding to survey modules and biometric measures.<br>• Check the completed Mapped Instrument documents provided by the Site Team to make sure the country-specific instruments are consistent with the corresponding dataset templates (question number, variable code, value labels and type for each variable). |

| Country Site Team | Evaluation Team |
|---|---|
| | • Guide (provide interviewer training guides, biometric measuring staff training guides, data entry guides) and assist (if needed) the Site Team to collect data based on CIH survey modules and biometric (physical and biochemical) measurements, as well as assist with engaging the schools, industry and health centres and obtain their support. |
| **STEP 4: Enter and clean data** | |
| • Perform ongoing quality assurance checks of data entered.<br>• Develop and run an error check programme. Double entry of at least 20% of all surveys is required (choose every 5$^{th}$ survey for double entry by a second data entry person).<br>• Re-keying will be necessary for improperly entered data. This is to make sure that the values for each variable are consistent with the value codes of the mapped instruments and data entry templates.<br>• Provide error check programme and output to Evaluation Team. | • Review error check programme provided by the country site. |
| **STEP 5: Manage and analyse data** | |
| • Upload data to FTP site as specified by the Evaluation Team.<br>• Discuss preliminary data outcomes with Evaluation Team in order. to direct and drive interventions.<br>• Review and analyse secondary variables. | • Track the data uploading by each Site Team and download them from the online survey software.<br>• Export datasets into the formats based on the analytical software and merge them if needed.<br>• Analyse primary variables (univariate overall and bivariate by age and gender) according to CIH Hypotheses and Indicators and create preliminary Data Book to provide to each Country Site.<br>• Create standard secondary variables for all sites to use for analysis. |

# 3. Preparation of the Data Collection Tools

## Organising data collection instruments

Depending on the setting and population being measured, survey modules should be organised into combinations of modules. These groupings of instruments are hereafter referred to as Survey Packages. It is critical that the Site Team strives to correctly label survey packages and set up a robust quality assurance system for efficiently and accurately collecting and managing data.

## Creating Survey Packages for Each Setting

The following table (Table 6) summarises which survey modules should be administered to each type of respondent in each setting.

**Table 6: Creating Survey Packages**

| Adults | Youth |
|---|---|
| Community members in Neighbourhood (Cross-sectional):<br>▪ *Adult Core Module*<br>Community members in Neighbourhood (Family Cohort):<br>▪ *Adult Core Module*<br>▪ *Cohort Module*<br>▪ *Biometric measures*<br>▪ *24-hour food and beverage recall (optional)*<br>Workers in Industry Workplace:<br>▪ *Adult Core Module*<br>▪ *Workplace Module*<br>▪ *Biometric measures*<br>Workers in Schools:<br>▪ *Adult Core Module*<br>▪ *Workplace Module*<br>Non-Clinical Workers in Health Centres:<br>▪ *Adult Core Module*<br>▪ *Workplace Module*<br>Clinical Practice Workers:<br>▪ *Clinical Practice Module* | School Children/Youth:<br>▪ *Youth Core Module*<br>▪ *Physical biometric measures*<br>School Children/Youth—subset:<br>▪ *Youth Core Module*<br>▪ *Youth Subset Module*<br>▪ *Biometric measures*<br>▪ *Previous Day Physical Activity Recall (PDPAR)*<br>▪ *24-hour food and beverage recall (optional)* |

## Labelling Surveys

Each survey will be coded with identifying information expressed as five variables in the dataset:

1) country site (COUNTRY)
2) data collection time point (TIME)
3) module type (MODULE)
4) participant identification number (ID)
5) region (Adult Module) or setting (Workplace, Clinical Practice, Youth Modules) code (REGION / SETTING)

**Table 7: Labelling Surveys**

| COUNTRY | TIME | MODULE | ID | REGION / SETTING |
|---|---|---|---|---|
| China=**1**<br>India=**2**<br>Mexico =**3**<br>UK= **4** | ▪ **T1**=baseline<br>▪ **T2**= 1st 6-month interval (Cohort)<br>▪ **T3**=2nd 6-month interval (Cohort)<br>▪ **T4**=3rd 6-month interval (Cohort)<br>▪ **T5**=follow-up | ▪ Adult Core **(A)**<br>▪ Neighbourhood Family Cohort **(F)**<br>▪ Workplace **(WP)**<br>▪ Clinical Practice **(C)**<br>▪ Youth Core **(Y)**<br>▪ Youth Subset **(S)**<br>▪ PDPAR **(P)**<br>▪ Biometric measures **(B)**<br>▪ Optional 24-hour food and beverage recall **(D)** | Adults in Neighbourhood<br>• **101000-102200** (intervention community), **201000-202200** (control community)<br>(Neighbourhood Cross-sectional)<br>• Numbers within the Cross-sectional sample (Neighbourhood Family Cohort)<br>Workers (not clinical practitioners) in Workplace<br>• **103000-104200** (intervention community), **203000-204200** (control community) (industry)<br>• **105000-106200** (intervention community), **205000-206200** (control community) (school)<br>• **107000-108200** (intervention community), **207000-208200** (control community) (health centre)<br>Clinical Practice Workers<br>• **109000-109999** (intervention community), **209000-209999** (control community)<br>School Children<br>• **110000-112400** (intervention community), **210000-212400** (control community) (School Children Core)<br>Numbers within the School Children Core sample (School Children Subset) | REGION<br>• Country-specific<br>SETTING<br>▪ **S1 – SN** (Schools, N=number of schools)<br>▪ **WP1 – WPN** (Workplaces, N=number of workplaces in site)<br>▪ **HC1 – HCN** (Health centres, N=number of health centres in site) |

As shown in Table 7, the participant identification numbers are sequenced by the type of participant (Adults as Community Members in Neighbourhood, Adults as Workers in Workplace, Clinical Practice Workers, School Children) and by site type (intervention community surveys always begin with '1' while control community surveys always begin with '2').

**The Country Site Team is responsible for keeping track of the identification numbers that correspond to each workplace, health centre, and school.** The participant identification number should appear on each survey instrument or interview completed by that participant, biometric measures contributed by that participant, and consent forms submitted by that participant[12]. It is critical that all participating individual have an independent identification number and that each number is 6 digits. The following provides the sequence for survey numbering. Note that the numbers include sampling for non-response and refusal rates and gaps are left between participant types as to allow for oversampling.

The multiple modules administered to the Neighbourhood Family Cohort (Adult Module and Cohort Module) should have the same ID number on the front covers. Likewise, all modules administered to workers (Adult Module and Workplace Module) should have the same ID on the front covers, and all modules administered to the school subset (Youth Module and Youth Subset) should have the same ID on the front covers. In this way, data for multiple surveys can be linked for a given individual.

As such, a string of variables

| [COUNTRY=1 TIME=T1 MODULE=WP ID=203031 SETTING=WP2] |
|---|

in the database can be identified as data from China from the baseline workplace survey completed by respondent 203031 in workplace #2, which is located in the control community. Using the participant identification number (203031) we know that data was completed by someone who works in an industry and thus should have also biometric form and consent forms. This individual's surveys would be coded as follows:

- *Consent Form* WP 203031
- *Workplace Module WP 203031*
- *Biometric measures B 203031*

While labelling of surveys may be done in many ways, we suggest that packets with the correct combination of modules are made for participants by type (venue) and then labelled as noted above. Each survey packet for industry workplaces, schools, and the Neighbourhood Family Cohort should contain a labelled consent form, as well as a labelled biometric measures sheet with the participant's unique identifier or card with the unique identifier which the participant will bring to the trained staff taking the biometric measurement. In this way, surveys and biometric measures can be linked.

Sites are encouraged to use other methods as they see fit, and to discuss possible alternatives with the Evaluation Team on a case-by-case basis.

[12] For sites using scanned scoring, the 6-digit ID must be incorporated into the forms. Any computer-generated labels should include 6 spaces for these participant IDs.

# 4. Data Collection: Surveys

## Distribution of Surveys

Surveys must be distributed to the following venues:

a. to schools (for adult 'workers' and school children),

b. to industry workplaces, and

c. to health centres (for adult 'workers' and 'health professionals').

A point-person within each venue should be identified prior to data collection. The Field Coordinator should meet with this point-person to discuss data collection operations and to identify dates for administration. The Field Coordinator may coordinate with the point-person to inform participants in these venues of the study purpose, participation, and protocol prior to data collection. The Field Coordinator may also work with the point-person to distribute and collect consent forms prior to data collection when necessary (e.g., such as in schools) and to ensure that all surveys are collected after completion. A bonus or incentive (tied to a certain % data return) is suggested for the point-person.

*IMPORTANT:*

In order to ensure privacy protection for all participants, consent forms should be stored separately from the survey and biomarker package. Instructions should be provided to all participants and interviewers to separate the consent form from the survey package once it is signed and store separately to ensure the protections of the participant's identity.

## Administration of Adult Surveys

### 1. Surveys for Neighbourhood

The **Adult Core Module** should be administered to 1,000 households as defined in *PART 2: Sampling Protocol*.

Data collection will occur over a 2-3 month period by 8+ trained interviewers (see the Interviewer Training Protocol for information on how to train these interviewers). All interviews will be administered via paper and pencil, laptop or personal digital assistants (PDAs). If administered via laptop or PDAs, the interviewers will conduct the survey verbally and fill in the respondent's answers directly onto the computer. If administered via paper or pencil, the interviewer will mark the respondent's answers on the paper survey.[13] Each question on the survey must be asked in the same style and manner for each person. The interview will be administered verbally in the local language/dialect that is the stated preference of the household member. It is expected that each interview will take approximately 30-40 minutes. As described in the *Sampling Protocol*, each household will receive a unique identifier that will be a data field variable for that interview. Interviewers should ensure that there is a unique identifier on each survey instrument.

### Steps for recruitment and survey administration

The interviewers will begin each interview by introducing the goals and objectives of the study, inviting the family to participate and selecting one individual to complete the survey (using the KISH method, Appendix D), walking through the informed consent process, answering any questions, and having the

[13] Face-to-face interviews rather than self-report are the preferred method of survey administration. In some circumstances, it may be cost prohibitive to administer face-to-face interviews. Under guidance from the Evaluation Team, a country site may use telephone or self-report surveys; however a validity study must be built in to compare the different methods.

selected individual complete and sign a consent form for participation in the study. (A suggested incentive is, once the survey is completed, enter the household into a raffle to win a prize that can be shared by the whole family.)

Interviewers will recruit participants during the weekdays, the evenings and/or the weekends. In scheduling time and day for household recruitment, the typical working hours of various community groups (ie, by socio-economic status and gender) must be considered to provide an equal opportunity for each household member to be sampled.

The protocol for participant selection and follow-up is taken from the WHO Steps Manual Interviewers Guide: Kish Method (please refer to the Appendix D).

**Using computer/PDAs:**

Each interview will be automatically saved on the computer/PDA and the interviewer will be asked to save each on a portable USB as a back up at the end of each day. (Please consult the Evaluation Team for instructions.) In addition, after every 10 interviews are completed, the interviewer will return to the study centre with signed consent forms and the PDA so data can be uploaded into the VOVICI system. Prior to data upload the Project Coordinator will make backup copies of the response file on a designated computer in the study centre and a copy of the file on to a CD-ROM and/or external hard drive and/or study centre server.

If a site uses a different mobile programme for the Vovici system, then the site is responsible for converting the data output into standard international format. All files should be backed up on at least 2 different sources.

**Using paper and pencil:**

Each interviewer should be provided with a waterproof folder to ensure that paper surveys are protected and secure. At the end of each day, interviewers should drop off the completed surveys at the study centre, logging in how many forms are being submitted and which households have been contacted. Each study centre should designate a mailbox for interviewers to drop off surveys during off hours.

### Data Tracking and Monitoring (with assistance from Evaluation Team)

***See the Data Entry section in this manual for details on the need for tracking surveys as they are completed and data entered.***

**Track data uploads:** The Field Coordinator must ensure that all interview data from the Neighbourhood Adult surveys is properly uploaded or entered into the country site's database by the interviewers. The Field Coordinator must check the database each week during data collection to ensure that each interviewer has uploaded or submitted their completed survey forms (including the **Interviewer Comment Sheets**) collected during that week to the study centre.

**Track demographics:** The Field Coordinator must track and update the age strata cells on frequently to ensure appropriate representation of various sub-populations within the community. Updates should be submitted to the Evaluation Team for review after every 200 interviews are completed and uploaded. The purpose of tracking demographics per every 200 interviews is to ensure that the site has an equal distribution of participants by age and gender; please see Table 2 in the Sampling Protocol for more detailed information.

**Track interviews:** The Field Coordinator should use the study database to assess the completion of scheduled interviews and the appropriate follow-up with households unable to participate at initial contact.

### 1A. Neighbourhood Family Cohort

During baseline data collection, a sample of 240 should be identified for the Neighbourhood Family Cohort Study. ***Eligibility for inclusion in the Family Cohort Study should be determined at the neighbourhood interview.***

Criteria should include:

1. Willingness to participate in further interviews and the Biometric Study.
2. Willingness to commit to a 2-year study with bi-annual check-ins and annual follow-ups.

The 240 families recruited from the neighbourhood cross-sectional study should be followed longitudinally over the course of the 2-year pilot study. In addition to completing the Adult Module and Cohort Module mentioned above, the Neighbourhood Family Cohort should participate in the Biometric Study. This includes physical and biological measurements taken by a specially trained field team (a lay interviewer and a medical practitioner). The Biometric Study should include, at a minimum, physical measurements – *height, weight, hip and waist circumference*, *blood pressure, and heart rate (some may also include skin-folds)*. *Rapid test for blood glucose, cholesterol (including LDL, HDL, total cholesterol),* and *triglycerides* should also be collected. Refer to Biological Measurement Protocol for specifics about this component of the study.

Participants who are screened as having higher than normal levels of glucose, cholesterol, or triglycerides should be referred to a clinic where blood samples can be taken for a thorough analysis. As mentioned above, the target individuals within each family for the Family Cohort study include one adult and, if possible, one youth. The adult is the informant for the household. An optional component includes administering the Youth Module and collecting physical markers from a youth (12 years of age or older) in the household.

As described above, in addition to the consent form, each adult survey packet prepared for the Neighbourhood Family Cohort should contain a labelled biometric measures sheet with the participant's unique identifier or card with the unique identifier which the participant will bring to the trained staff taking the biometric measurement. In this way, surveys and biometric measures can be linked.

### 2. Surveys for Workplace

Adults in workplaces (schools, industry, and health centres) will be administered the Adult Module and the Adult Workplace Module. Workers from industry workplaces will also contribute biometric measurements for the Biometric Study. Each survey should have a title page with bold print instructing participants to read and completed the consent form before proceeding to the survey. Any surveys that are completed without accompanying signed consent forms should be shredded.

Each Site Team should designate an individual (a Field Coordinator) to be responsible for distributing and gathering these surveys at baseline and during the follow-up intervals. One staff person should be identified as the point person at each workplace to assist the Field Coordinator with internal operations coordination.

### 2a. Workplace Schools

In the CIH programme, the school setting is considered to be a workplace setting reflective of places of employment in the community at large. School employees of the selected schools, including administrators, teachers, nurses, and other school staff, should complete the survey. The target sample size is between 700-1,000 teachers and support staff (intervention and control) per country site. All selected school employees should complete the Adult Module and Adult Workplace Module.

One staff person should be identified as the point person at *each* school to assist in coordinating survey administration.

**2b. Workplace Industry**

As described in the Sampling Protocol, each site is responsible for identifying and selecting appropriate industry locations. The Field Coordinator and principal researchers at each site are responsible for contacting the industries and inviting them to participate in the study. The Evaluation Team will work with the site to provide some technical assistance to achieve this objective (eg, assisting with designing letters to industry, participating in any required meetings with industry). Whenever possible, the Field Coordinator should work directly with the Human Resources Department of the industry and/or the industry's health staff to determine the most efficient method for distributing and collecting surveys, completing the biomarker study, and providing access to project staff to ask questions prior to signing the consent forms.

The target number for each CIH site is 1,000 employees from industry for each group (intervention and control). Selected employees from industry should complete the consent form, the Adult Core Module, and the Workplace Module as well as participate in the Biometric Study, which includes physical and biological measurements. Each employee who completes the self-administered surveys should be eligible for an incentive such as a raffle draw that will occur at the end of the baseline data collection period. Informed consent from each employee should be obtained prior to completing the survey and Biometric Study (refer to Biological Measurement Protocol).

The Biometric Study at industry includes at a minimum, the assessment of *height, weight, hip and waist circumference, blood pressure, heart rate, and skin-folds (optional)*. *Rapid test for blood glucose, LDL, HDL, total cholesterol, and triglycerides* will also be collected. Participants who are screened as having higher than normal levels of glucose, cholesterol, or triglycerides will be referred to a clinic where blood samples can be taken for a thorough analysis. The Biometric Study may be conducted by the research teams at each CIH site if an arrangement is not possible with the industry and/or they do not have health staff. The Field Coordinator should be available onsite at designated periods during health fairs to respond to questions about the survey or study.

As described above, in addition to the consent form, each adult survey packet prepared for industry workplaces should contain a labelled biometric measures sheet with the participant's unique identifier or card with the unique identifier which the participant will bring to the trained staff taking the biometric measurement. In this way, surveys and biometric measures can be linked.

**2c. Workplace Health Care Facilities**

As described in the Sampling Protocol section, one or more large hospital(s)[14], 10 health centres, or a combination of hospital(s) and health centres will be identified for intervention within each CIH site and will be invited to participate in the study. If the Site Team has included all the health care facilities in both the intervention and control areas and is not able to reach the target sample size, the Site Team should consult with the Evaluation Team to discuss alternative methods. Similar to the Workplace Industry protocol, the health care facilities should select a sample from all non-clinical employees to complete a consent form as well as the Adult Core Module and Workplace Module. The surveys will be self-administered and distributed by the Field Coordinator to each of the selected centres.

[14] It is expected that there will be 1,000 surveys completed by workers, thus, unless 100% participation is expected, the centre must have well over 1,000 employees.

### 3. Surveys for Clinical Practice Workers in Health Care Facilities

The Clinical Practice Module should be self-administered to all clinical medical staff, specifically doctors and nurses, at the selected health care facilities. The Evaluation Team will work with each CIH site to develop a strategy for engaging the health care facilities and gaining their support for the project.

As mentioned in the above section, non-clinical employees from each of the selected health care facility should complete the Adult Core Module and Workplace Module.

## Administration of Youth Surveys

Refer to the *Sampling Protocol* for details on school sampling and selection. Briefly, study surveys will be administered at up to 20 schools to a total of approximately 2,400 students, for each group (intervention and control) within each CIH country site (includes an additional 20% for potential non-response). Although the CIH school interventions will target youth of all ages, knowledge, attitudes, and beliefs will be measured in youth aged 12 and 14. Thus, surveys should only be administered to youth in the two grades where students are predominately 12 *and* 14 years old. Depending upon the size of the student body at each school, one of the following methods should be employed at each school:

- Two classes from the two grades in which most of the students are 12 *and* 14 years old should be selected.
- The entire two grades in which most of the students are 12 *and* 14 years old should be selected.

Once the schools sampling frame is set, the site Project Coordinator should serve as the primary liaison to the schools and should contact the Headmasters to inform them of the study and invite them to participate. Where possible, the Evaluation Team may provide technical assistance in drafting letters and/or attending meetings/teleconferencing to assist with gaining buy-in.

Informed consent for children to participate should occur in advance of the baseline data collection by sending out letters to parents to inform them of the goals and objectives of the study. The informed consent process may include passive or active consent depending on the ethical review board processes of individual countries. If active consent is required, the student ID must be on the consent form (this may occur before or after it has been submitted by parent/adult). The student ID may be added to the consent form by individually distributing surveys to students and copying the ID on the survey they receive onto their consent form.

As described above, each survey packet prepared for youth will contain a labelled survey, completed and labelled consent form, and a labelled sheet with a unique identifier or card with a unique identifier that matches their Youth Core Module identifier, which the participant will bring to the trained staff giving them the biometric measurements. Three large envelopes should be provided for each participating classroom – completed surveys and consent forms will be put in these envelopes. Completed Consent Forms should be placed in one envelope, completed surveys with Consent Forms should be placed in another envelope, and completed surveys without Consent Forms; each envelope should be marked according to the contents (Consent Forms, Surveys with Consent Forms, Surveys without Consent Forms). Any Youth Modules without accompanying signed consent forms will be shredded by the research team (ie, all the surveys in the envelope marked Surveys without Consent Forms).

In addition to the Youth Core Module, all children in selected classrooms or grades will undergo the physical measurements of the Biometric Study in which *height, weight, hip and waist circumference, blood pressure, and heart rate* will be obtained either with the assistance of the school health staff or

the research team. Skin-fold measurements are encouraged but optional. (Refer to *PART 5.5: Physical and Biological Measurement Protocol* below).

As an in-depth study, a small subset of 200 students across all schools will be selected to complete a previous day physical activity recall (PDPAR) and 24-hour food and beverage recall (optional). Sites will randomly select classrooms across all participating schools from a subset of students whose parents have agreed to their participation. These students will take these surveys home to be completed with the assistant of an adult household member.

As mentioned previously, staff from each of the selected schools will be asked to complete the Adult Core Module and Workplace Module.

# 5. Data Collection: Physical and Biological Measurements

## Introduction

To assess relationships between physical health and interventions targeting unhealthy diet, physical inactivity, and tobacco use, CIH includes a Biometric Study, in which physical and biological measurements for participants in both the intervention and control communities will be collected. The Biometric Study is based on the World Health Organisation's STEPwise approach (STEPS) and the INTER-HEART global study of risk factors for acute myocardial infarctions.

While the physical measurements for the study are non-invasive, the biological measurements rely on blood specimens collected on test strips using rapid screening tools. The only addition to the STEPS measures for this study is the introduction of the skin-fold calliper as a tool to measure body fat. Procedures for the collection of physical and biological measurement follow those outlined in the STEPS Manual[15] and the INTER-HEART study protocol[16]. Measurements for this study correspond with those for the Expanded STEPS protocol. Skin-fold procedures are noted below.

Once collected, physical and biological measurements will be matched to completed participant surveys or interviews using unique identifiers assigned based on the relevant administration protocol. Staff collecting the physical and biological measurements will record measurements using the participants' unique identifiers on the data recording forms provided.

## Physical Measurements

All forms must be labelled appropriately to ensure all results and samples can be linked with surveys and biological measurement forms (see *PART 5.3: Preparation of the Data Collection Tools*).

### Sequence of tests

Physical measurements should be conducted prior to drawing blood for biological measurements. Physical measurements should be taken from the participant in the following order:

- Height
- Weight

[15] World Health Organization. 2006. STEPS User Manual. The most relevant information for the physical and biological measurements may be found in Part 3, Sections 4 and 5.
[16] INTER-HEART 2001 Instruction Manual. The most relevant information for the physical measurements may be found in section 5 page 22.

- Waist circumference
- Hip circumference
- Heart rate
- Skin-fold (if possible); and
- Blood pressure

### Units of measurement

Table 8 below shows the standard units for physical measurements and their upper and lower limits for data entry purposes.

**Table 8: Standard units for Physical Measurements**

| Physical Measure | Unit | Minimum | Maximum |
|---|---|---|---|
| Height | cm | 100 | 270 |
| Weight | kg | 20 | 350 |
| Waist circumference | cm | 30 | 200 |
| Hip circumference | cm | 45 | 300 |
| Heart (Pulse) rate | beats/minute | 30 | 200 |
| Skin-fold measures | mm | 0 | 85 |
| Systolic blood pressure (SBP) | mmHg | 40 | 300 |
| Diastolic blood pressure (DBP) | mmHg | 30 | 200 |

### Necessary Equipment

- Non-stretchable measuring tape
- OMRON (Digital Automatic Blood Pressure Monitor DABPM)
- Stethoscope
- Skin-fold calliper
- Platform scale

All sites should consult with Evaluation Team in the selection of the equipment used.

### Privacy

Whenever possible, all physical measurements should be conducted in a private area. In settings where this might not be possible, at a minimum, privacy should be ensured by using screens when measuring waist and hip circumference and skin-folds.

Participants should be allowed to determine the degree of privacy necessary for their participation in the study. For example, some people may prefer to use a privacy screen; while others may not want to go behind a screen or out of the sight of others with study personnel who they do not know. Participants should feel reasonably comfortable while having physical and biological measurements collected.

### Introductions and explanations

Prior to taking physical measurements, explain what measurements you will be taking, and describe how. These procedures are described in both the consent form and the STEPS manual (Part 3, Sections 4-5). Details about each of the measures follows.

### Measuring Height

Standing height is measured with the participants in bare feet, their back square against the wall and their eyes looking straight ahead. A set square resting on the scalp and a tape measurement from the wall is used to measure height to the nearest 0.5 cm. Head gear (hats, caps, combs, ribbons, but not headscarves) should be removed for the measurement.

For improved precision and reliability in taking measurements site can use a portable stadiometer. Please consult with the Evaluation Team on equipment selection.

### Measuring Weight

Weight is measured using a portable electronic scale. Scales should not be placed on a carpet or sloped, rough or uneven surface. For uneven surfaces, a stiff board may be used to level the surface. Weight will be measured with participants in bare feet and without heavy garments like coats. Participants should remove all items from their pockets and should not carry anything while being weighed. Scales should be tared before each measure.

### Waist Circumference

Waist circumference is measured to the nearest 0.1 cm using a non-stretchable, standard tape measure attached to a spring balance exerting a force of 750 gm. Take the measurement over the unclothed abdomen or over a light article of clothing if participants are uncomfortable exposing their abdomen. The measurement should be taken at the smallest diameter between the costal margin and the iliac crest (that is, under the midline of the participant's armpit, at the midpoint between the lower part of the last rib and the top of the hip). The tape measure must be kept horizontal. Participants should relax with arms held loosely at their sides and measurements should be taken at the end of a normal expiration. Two (2) measurements should be recorded.

If a sites uses a special girth-measuring tool, such as the SECA 200 Circumference Measuring Tape, steps to standardise measurements (attaching spring balance) do not need to be followed as the equipment has an automatic retraction that automatically standardises measurements. Two (2) measurements should be recorded.

### Hip circumference

Hip circumference is measured to the nearest 0.1 cm using a non-stretchable, standard tape measure attached to a spring balance exerting a force of 750 gm. Measurements should be taken over light

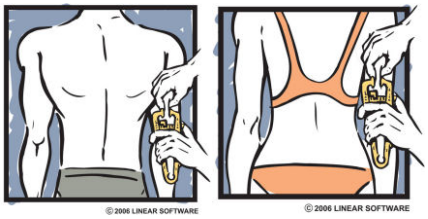
clothing at the level of the greater trochanters (usually the widest diameter around the buttocks). The tape measure must be kept horizontal. Two (2) measurements should be recorded.

If site used special girth measuring tool such, as the SECA 200 Circumference Measuring Tape, steps to standardise measurements (attaching spring balance) do not need to be followed as the equipment has an automatic retraction that automatically standardises measurements. Two (2) measurements should be recorded.

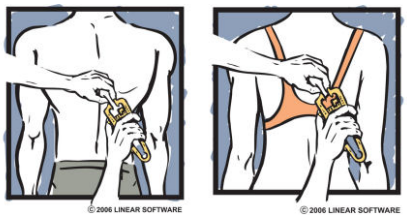
### Skin-fold

Skin-fold measurements should be taken at the 2 standard sites: triceps and subscapular for both men and women. Each measurement should be repeated three times to avoid measurement error. A standard skin-fold calliper should be used and calibrated at the beginning of each day.

- Triceps – Have the participant bend their elbow at a ninety degree angle (from the top shoulder acrosion process which is a bony process at the top of the shoulder to the base of the elbow). Mark the mid-point with eyeliner or washable marker. Using the reference mark, make a ***vertical*** fold on the triceps, taking care not to pinch the muscle. Use the calliper to measure the fold or excess skin. Take two recordings with the calliper.




- Subscapular – This fold is measured on the diagonal line from the vertebral border to between 1 and 2 cm from the inferior angle of the scapulae. (A diagonal fold about 1 to 2 cm below the point of shoulder blade and 1-2 cm towards the arm.) Grasp a fold of skin. Place the jaws of the calliper perpendicular to the length of the fold, about 1.0 cm lateral to the fingers. Measure the skin-fold thickness to the nearest 1 mm. Record the measurement. Take the measurement again, and record. If two measurements are within 4 mm of each other, record the mean. If the measurements are more than 4 mm apart, take four measurements and record the mean of all four.




*IMPORTANT***:** There is considerable variability that can occur if the skin-fold measures are not taken correctly. It is therefore essential that field staff knows and has demonstrated he/she knows the correct procedure before going into the field.

### Blood Pressure

Participants should be in seated position while measurements are taken. Participants cannot smoke in the 30 minutes prior to this test and must be resting for 5 minutes or more before the measurements are taken. Staff should ensure that various cuff sizes are available for all potential participants.

**Table 9: Blood Pressure Cuff Sizes**

| Arm Circumference (cm) | Cuff Size |
|---|---|
| 17 -22 | Small (S) |
| 22-32 | Medium (M) |
| > 32 | Large (L) |

The cuff bladder should encircle and cover 2/3 of the length of the arm, with the bladder over the brachial artery. Its lower border should be 1 inch (2-3 cm) above the anticubital space. Three readings should be taken on the left arm, at least 3 minutes apart, and be recorded as exact values. Do not round measurements upward or downward—record the exact measurement. The mean of the 2nd and 3rd readings should be used for analysis.

### Heart Rate

Measure pulse using the radial artery, felt at the wrist, on the right arm. Count the number of heartbeats during 10 seconds and multiply by 6. Participants should not have smoked for at least 30 minutes before this measurement. Two (2) recordings should be taken.

## Biological Measurements

### Introduction

All samples and forms must be labelled appropriately to ensure all results and samples can be linked with questionnaire and physical measurement forms. Blood samples are taken from eligible participants to be used to perform simple tests to measure blood glucose and lipid profile (total cholesterol, LDL, HDL and triglycerides). The simple biological tests being used in this study are all rapid tests, which use whole blood samples drawn using capillary tubes and collected on test cassettes . There is no need to collect or store blood for this study as blood test results will be recorded immediately.

### Infection Control

Universal precautions should be adopted when drawing blood and disposing of sharp objects that have been in contact with blood. Gloves and a biohazard disposal bin must be available at each testing site. Whole blood is more infective in terms of blood borne disease than centrifuged serum or plasma. Used test strips containing blood should also be discarded immediately after recording the measurement.

### Why do we need blood testing?

Chronic diseases are progressive and develop over a lifetime; therefore, there is often a lengthy asymptomatic phase prior to diagnosis. (Figure 5) Even the best health surveillance system may

under-estimate the true burden of chronic disease in the general population. Current evidence suggests that up to 50% of type 2 diabetes cases in developed countries is undiagnosed.[17] Epidemiologic modelling has shown that one-third of type 2 diabetes cases are undiagnosed in England.[18]

Total cholesterol, triglycerides and glucose levels in the blood are proximal indicators for future onset of cardiovascular disease and diabetes, respectively. Without conducting a blood test to measure cholesterol, triglycerides, and blood glucose levels there is no way of for the CIH programme to comment on the long-term impact of the interventions on disease incidence and outcomes.

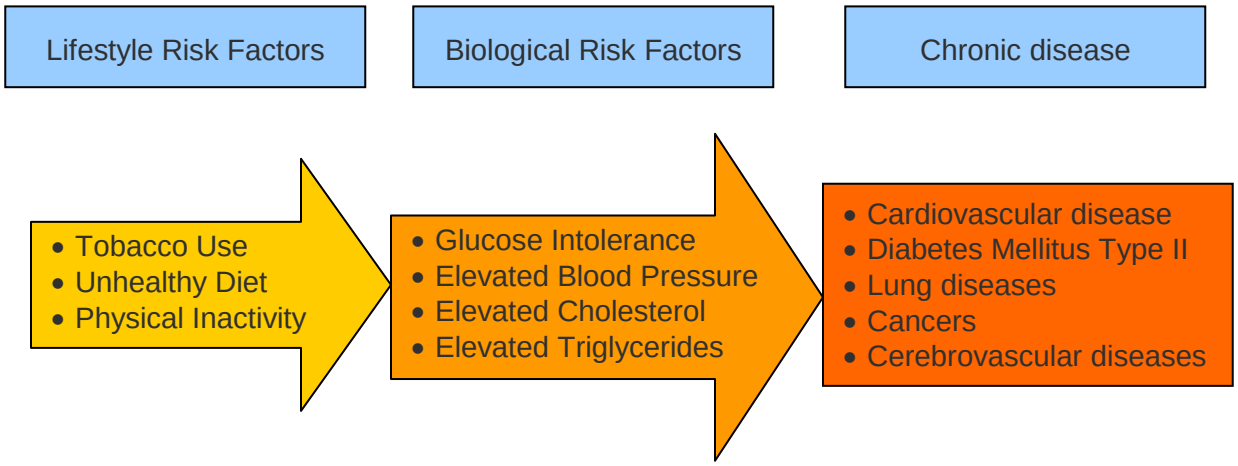



**Figure 5: Model showing the progression from lifestyle risk factors to disease.** The biological risk factors are proximal indicators for a chronic disease, as well as proximal indicators for disease outcomes for those who have already been diagnosed with a chronic disease.

### Units of measurement

Table 10 below shows the standard units of measurement for biological measurements and their upper and lower limits for data entry purposes.

[17] King H, Rewers M. Global estimates for prevalence of diabetes mellitus and impaired glucose tolerance in adults. WHO Ad Hoc Diabetes Reporting Group.*Diabetes Care* 1993;**16** : 157–177.

Harris MI. Undiagnosed NIDDM: clinical and public health issues.*Diabetes Care* 1993;**16**: 642–652.

[18] Forouchi N.G, Merrick D., Govdert E., Fergurson., Abbas J., Lachoqycz and Wild S.H. Diabetes prevalence in England, 2001-estimated from an epidemiological model. *Diabetic Medicine* 2005; **23**; 189-197

**Table 10: Standard units for Biological Measurements**

| Blood Test | Unit | Minimum | Maximum |
|---|---|---|---|
| Fasting glucose | mmol/L | 1 | 35.0 |
| Random glucose | mmol/L | 1 | 50.0 |
| Total cholesterol | mmol/L | 1.75 | 20.0 |
| HDL | mmol/L | 0.10 | 5.0 |
| LDL | mmol/L | 0.10 | 5.0 |
| Triglycerides | mmol/L | 0.25 | 50.0 |
| Total cholesterol/HDL ratio | | 1.10 | 30.0 |

### Participant's instructions

To obtain accurate results, participants must fast for at least eight (8) hours before blood collection, when possible. If it is not possible to obtain samples from fasting blood, a notation must be made. Diabetic patients on medications are required to bring their tablets with them and to take them after their blood measurement if possible. If individuals with diabetes who are on medications have not brought their medications with them, they should inform the staff.

*IMPORTANT:*

- Before taking measurements, field staff should confirm that the participant has fasted for at least 8 hours.
- All forms used to record results should be labelled appropriately (see *PART 5.3: Preparation of the Data Collection Tools*).
- All participants should have signed a consent form prior to having measurements taken.

### Necessary Equipment

Dry chemistry equipment and supplies required for blood glucose tests include:

- Lipid Profile + GLU test cassettes
- LDX system
- Capillary tubes and plunger
- Disposable needles for lance
- Test strips
- Sterile swabs
- Cotton balls
- Disposable container with a lid
- Latex or vinyl gloves

### Measurement procedure

The LDX system is an all in one test system which requires sample to be drawn only once for all the tests. Each reading takes 5 minutes to process.

For staff, certain precautions should be taken. Staff must wash their hands with warm water before the measurement because contamination with glycerol from hand lotions, soaps, or disinfectants will interfere, producing a positive bias. In addition, blood drops must be obtained strictly according to the instructions because excessive "milking" may dilute the concentration of the analysis with lymph or interstitial fluid.[19] Procedures for collecting blood for the rapid tests follow.

1. Open the drawer and take out the testing cassette.
2. Rub and kneed a fingertip to help withdraw blood (use the side of your pointer finger).
3. Wipe or swab the fingertip with a sterile swab.
4. Load the lance with a new needle; lance the massaged place on the fingertip with the lancing device.
5. Draw the excess blood using the capillary tube keep mind to close one of plunger in order to create force necessary to draw the blood in the tube. **NOTE:** it is important that enough blood is drawn in order to get an accurate reading make sure the capillary tube is filled to the marked line.
6. Give the participant a cotton ball to press on the punctured area.
7. Release the blood sample in the capillary tube in the well of the cassette; use the plunger to get remaining blood from the capillary tube.
8. Dispose the capillary tube in the appropriate biohazard disposal unit.
9. Place the cassette in the drawer and hit “Run”. The test will take 5 minutes.
10. Record the results of the test in the participant’s Biological Measures Form.
11. Remove the test strips and discard in the appropriate container.
12. Cap the needle and discard in the needle disposal unit.

## Labelling

Each participant survey will include a sheet of printed identification labels. Participants will bring labelled sheets to staff for physical and biological measurements. The clinician will use the label provided by participants to label physical and biological measurement forms.

[19] Claus Luley, Gunnar Ronquist, Wolfgang Reuter, Valerie Paal, Hans-Detlev Gottschling, Sabine Westphal, George L. King, Stephan J.L. Bakker, Robert J. Heine, and Andrew Hattemer. **Point-of-Care Testing of Triglycerides: Evaluation of the Accutrend Triglycerides System** Clin Chem 2000 46: 287-291.

# 6. Preparation of the Database

As noted in Table 5: Data Collection Tasks and Responsibilities (*PART 5.2 Data Collection and Management Protocol*), the Evaluation Team will provide each CIH country site with Mapped Instruments and SPSS templates that match the International (generic) surveys. Each site is then responsible for adapting each of these to each country-specific survey module. It is very important that the adapted Mapped Instrument and SPSS template match the country-specific surveys, as well as each other. These tools will be used for data entry, data management, and data analysis, and so it is vital that they are accurate and that they match each other to avoid confusion.

Please refer to the *PART 1.3: Translation Protocol, Textual Adaptations* for details on how to prepare the Mapped Instrument. Below are instructions for preparing (modifying) the provided SPSS templates.

## Modifying SPSS Templates

Generic CIH SPSS templates are available upon request from the Evaluation Team. Each country site is responsible for adapting and modifying the generic SPSS templates to match their country-specific surveys. This may also include programming any skips into Epidata as desired by the country site team.

The generic SPSS templates provided by the Evaluation Team match the generic surveys; country-specific response options are included. **It is very important to make sure to delete these country-specific response options if they are not utilised, or to adapt them as necessary.** Also, if a country site has added additional response options to a question, or has added additional questions, these modifications should be done in the SPSS template.

## Data Entry using Epidata

We recommend that all country sites use the SPSS data entry templates provided by the Evaluation Team for data entry. However, if a country site prefers to use Epidata for data entry, the SPSS template needs to be converted into an Epidata entry template. The following is the procedure for generating the Epidate template from the provided SPSS template:

- Adapt the standard SPSS template provide by the Evaluation Team
- Save the SPSS revised template file as a “STATA” file (versions 6+ should work). NOTE: the SPSS you use must be Version 15 or higher one.
- In Epidata software, click “Data in/out” in the toolbar, and select “Import”→”Stata”. In the opened window, select and open the appropriate “STATA” file created in the last step. Then four Epidata files will be generated: “.dta”, “.rec”, “.not” and “.chk”.
- Under the path you saved the Epidata files, select the “.rec” file and “Open with” Notepad or other plain text programme. If there is “_” before the variable name “q..z..”, delete the “_” but make sure keep the variable name and label, then resave the file and close it.
- In the toolbar of Epidata software, click “Tools” and select “QES File from REC file”. In the “Create .QES file from data file” box, make sure the file in “Create from data file” is the file saved in last step and the “Name of new .QES file” is saved in the appropriate location with a name you choose (it’s recommended to keep the same name as that of the “.rec” file). Here a new Epidata file “.qes” file has been created.

- Go to “1.Define Data” and “Open .QES file”. Delete the “.####” in each line of the “.qes” file to make the data fields the appropriate width for data entry.
- Then go to “Make Data File” and click “OK” in the pop-up “Create data file from .QES file” box. A prompt will ask if you want to overwrite the file. Click “OK” twice. Enter a description of the data file in the “Data file label” box and click “OK”.
- Additional validation and skips can be programmed into the Epidata form.
- Now you are ready to enter the data in Epidata.

# 7. Data Entry and Management

## Data Entry Training and Quality Checks

The Site Team is responsible for training data entry staff, and conducting a quality check on survey data entered by hand. The purpose of this check is threefold: to assess the data entry error rate, to identify types of errors, and to inform retraining of data-entry staff.

After the first stack of 200 surveys (Batch 1) is entered, every 5$^{th}$ survey should be pulled and re-entered (by a different data entry staff member). For every batch of 500 surveys thereafter, every 5$^{th}$ survey should be pulled and re-entered by a second data entry person. Results should be compared for reliability and common errors. Data entered by each data entry staff member should be checked for quality.

Quality check results (reliability and common errors) should be submitted to the Evaluation Team after each batch (ie, after the first 200 surveys entered and then after every 500 surveys entered thereafter). Any inconsistencies should be corrected in the main database.

These quality checks are to make sure that the data entered (and subsequently analysed) is consistent with the answers given by participants.

## Data Cleaning

The Site Team is responsible for developing and running an error check programme either in Epidata or in another programme. Re-keying will be necessary for improperly entered data.

This is to make sure that the values for each variable are consistent with the value codes of the mapped instruments and data entry templates.

## Sending Data to the Evaluation Team

The data set submitted to the Evaluation Team must by in English, and must follow the standard coding structure in the SPSS template provided by the Evaluation Team. For each module, data should be sent in batches of 500 surveys (the first batch, however, should include the first 200 surveys collected and entered). Each batch should be mutually exclusive; for example, the first batch will include the first 200 surveys entered (1-200), the second batch will include the *next* 500 surveys entered ONLY (surveys 201-700), the third batch will include the *next* 500 surveys entered ONLY (surveys 701-1200), and so on.

Each dataset should be saved using the following naming convention for file names:

COUNTRY_Module_BatchNumber.sav

For example, the SPSS file saved as CHINA_Adult_B1 would correspond to Batch #1 of the Adult Module data, sent from China.

All sites will send the data in SPSS format by secured FTP site, as well as mail a CD with all the data set and all documentation for all study data. CIH Programme, Matrix Public Health Solutions, 794 Edgewood Ave, New Haven, Connecticut, 06515 USA

Please contact the Evaluation Team to obtain your site's username and password in order to access the FTP site where data will be uploaded and/or if your site encounters any technology challenges.

# APPENDICES

## APPENDIX A: Document of Suggested Changes

**(to be submitted by Translator B to Site Team after back-translation)**

**Site Location (city and country):** _____

**Translator's Name:** _____ **Date:** _____

| **Module** _____ | | |
|---|---|---|
| **Question Number** | **Comment** | Suggestion applied? (for site team use only) |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

# APPENDIX B: Sample Mapped Instrument Page

| General Health | | | Response Choices | | Code (variable name) | |
|---|---|---|---|---|---|---|
| **CIH Q No.** | **Site Q No.** | **CIH Generic Question** | **CIH Generic** | **Site Specific** | **CIH Generic** | **Site Specific** |
| 1 | | How tall are you without your shoes on? | Numeric (meters) (should be a positive real number)<br>Missing [0] | | Q1Z1 | |
| 2 | | How much do you weight without your shoes on? | Numeric (kilograms) (should be a positive real number)<br>Missing [0] | | Q2Z1 | |
| 3 | | How would you assess your present state of health? | Very poor [1]<br>Poor [2]<br>Average [3]<br>Good [4]<br>Very good [5]<br>Excellent [6]<br>Missing [0] | | Q3 | |
| 4 | | Are you currently covered under any health insurance? | Yes, I have full coverage [1]<br>Yes, I have partial coverage [2]<br>No, I do not have Coverage [3]<br>Missing [0] | | Q4 | |

# APPENDIX C: Site-Specific Estimates of Sample Size

## CHINA-SPECIFIC ESTIMATES OF SAMPLE SIZE AND ESTIMATE PRECISION AT 80% POWER (GENDER-SPECIFIC)

| | China Adults | | | | China Children | | | |
|---|---|---|---|---|---|---|---|---|
| | *Males* | | *Females* | | *Males* | | *Females* | |
| Power Level | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval |
| Tobacco use | **1085**[20] | 4.33 | **285**[21] | 1.72 | **170**[22] | 2.08 | * | * |
| Unhealthy Diet | **320**[23] | 1.91 | **245**[24] | 1.49 | **1045**[25] | 4.2 | **995**[26] | 4.08 |
| Physical Inactivity (IPAQ inactive) | **245**[27] | 2.51 | **360**[28] | 2.84 | **555**[29] | 3.36 | **495**[30] | 3.21 |

* Pre-intervention rate is only 2% for female youth

[20] Starting prevalence=.57
[21] Starting prevalence=.04
[22] Starting prevalence=.06
[23] Starting prevalence=.95
[24] Starting prevalence=.97
[25] Starting prevalence=.64
[26] Starting prevalence=.68
[27] Starting prevalence=.09
[28] Starting prevalence=.12
[29] Starting prevalence=.18
[30] Starting prevalence=.16

## INDIA-SPECIFIC ESTIMATES OF SAMPLE SIZE AND ESTIMATE PRECISION AT 80% POWER (GENDER-SPECIFIC)

| | India Adults | | | | India Children | | | |
|---|---|---|---|---|---|---|---|---|
| | *Males* | | *Females* | | *Males* | | *Females* | |
| Power Level | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval | 80% | 90% |
| Tobacco use | **1085**[31] | 2.97 | **170**[32] | 3.83 | **320**[33] | 3.43 | | |
| Unhealthy Diet | **1050**[34] | 2.99 | **1095**[35] | 2.95 | | | | |
| Physical Inactivity | **955**[36] | 3.02 | **615**[37] | 3.1 | | | | |

[31] Starting prevalence=.50
[32] Starting prevalence=.07
[33] Starting prevalence=.11
[34] Starting prevalence=.43
[35] Starting prevalence=.51
[36] Starting prevalence=.35
[37] Starting prevalence=.20

## MEXICO-SPECIFIC ESTIMATES OF SAMPLE SIZE AND ESTIMATE PRECISION AT 80% POWER (GENDER-SPECIFIC)

| | Mexico Adults | | | | Mexico Children | | | |
|---|---|---|---|---|---|---|---|---|
| | *Males* | | *Females* | | *Males* | | *Females* | |
| Power Level | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval |
| Tobacco use | **965**[38] | 3.02 | **460**[39] | 3.26 | **860**[40] | 3.06 | **820**[41] | 3.07 |
| Unhealthy Diet | | | | | | | | |
| Physical Inactivity (IPAQ inactive) | **495**[42] | 3.23 | **555**[43] | 3.19 | | | | |

[38] Starting prevalence=.36
[39] Starting prevalence=.15
[40] Starting prevalence=.30
[41] Starting prevalence=.28
[42] Starting prevalence=.16
[43] Starting prevalence=.18

## LEICESTER-SPECIFIC ESTIMATES OF SAMPLE SIZE AND ESTIMATE PRECISION AT 80% POWER (GENDER-SPECIFIC)

| | Leicester Adults | | | | Leicester Children | | | |
|---|---|---|---|---|---|---|---|---|
| | Males | | Females | | *Males* | | *Females* | |
| Power Level | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval | 80% | Conf Interval |
| Tobacco use (Leicester) | **800**[44] | 3.07 | **585**[45] | 3.17 | **670**[46] | 3.13 | **840**[47] | 3.06 |
| Unhealthy Diet (Region which includes Leicester) | 495[48] | 2.64 | 585[49] | 2.72 | | | | |
| Unhealthy Diet (Leicester) | 840 (overall no gender-specific rates)[50] | 2.85 | | | | | | |
| Less than 30 mins 5d/wk (UK - Leicester Obesity Report) | 1050[51] | 2.92 | 880[52] | 2.86 | **615** (overall no gender-specific rates)[53] | 2.64 | …. | |
| Less than 30 mins 5d/wk (Leicester - Leicester Obesity Report) | 900 (overall-no gender-specific rates)[54] | 2.87 | ……. | | | | | |

[44] Starting prevalence=.27
[45] Starting prevalence=.19
[46] Starting prevalence=.22
[47] Starting prevalence=.29
[48] Starting prevalence=.90
[49] Starting prevalence=.87
[50] Starting prevalence=.77
[51] Starting prevalence=.63
[52] Starting prevalence=.75
[53] Starting prevalence=.20
[54] Starting prevalence=.74

# APPENDIX D: Kish Household Coversheet and Kish Method Examples

**Directions**

List the sex and age of all adults in the household aged 18-64 years in the empty table below. To complete the Rank column, order all adults in the list by:

- males in order of decreasing age (oldest to youngest)
- females in order of decreasing age (oldest to youngest)

Example:

| Sex | Age | | Rank |
|---|---|---|---|
| M | 45 | | **1** |
| F | 47 | | **3** |
| M | 23 | | **2** |
| F | 35 | | **4** |

In the **Kish Selection Table** find the square whose column heading matches the last digit of the Household Number and whose row heading matches the total number of eligible persons in the household. The person whose Rank matches this number is the selected participant for this household.

---

**List all persons age 18-64 in household**

| Sex | Age | | Rank | Selected Respondent |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Full physical household address:

_____

_____

Household Number _____

Cluster Number_____

Participant ID _____

### Kish Selection Table

| Number of Eligible Persons in Household | Last Digit of Household Number | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| **1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **2** | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 |
| **3** | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| **4** | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 |
| **5** | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| **6** | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 |
| **7** | 5 | 6 | 7 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **8** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 |
| **9** | 8 | 9 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| **10** | 9 | 10 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

**EXAMPLE 1**

The interviewer is going to select a participant in Cluster #3, Household #17. In this household, there are 4 people, aged 23(F), 54(M), 52(F) and 83(F) years, respectively. Then the Kish Household Coversheet would be like:

**List all persons age 18-64 in household**

| Sex | Age | | Rank | Selected Respondent |
|---|---|---|---|---|
| F | 23 | | 3 | |
| M | 54 | | 1 | √ |
| F | 52 | | 2 | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Full physical household address:

_____

_____

Household Number _17_____

Cluster Number_3_____

Participant ID

Since the selected participants should be aged between 18 and 64, the 83-years-old female should be excluded.

In the following table, Household #17 which last digit is 7, so it corresponds to Column 7. There are 3 eligible participants in the household, so it corresponds to Row 3. Using Kish Selection Table, the interviewer will select #1 to take the survey, i.e., the 54-years-old male.

**Kish Selection Table**

| Number of Eligible Persons in Household | Last Digit of Household Number | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| **1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **2** | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 |
| **3** | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| **4** | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 |
| **5** | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| **6** | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 |
| **7** | 5 | 6 | 7 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **8** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 |
| **9** | 8 | 9 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| **10** | 9 | 10 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

**EXAMPLE 2**

The interviewer is going to select a participant in Cluster #5, Household #23. In this household, there are 8 people, aged 11(F), 20(M), 23(F), 47(M), 49(F), 54(M), 85(F), 92(M) years, respectively. Then the Kish Household Coversheet would be like:

**List all persons age 18-64 in household**

| Sex | Age | | Rank | Selected Respondent |
|---|---|---|---|---|
| M | 20 | | 5 | |
| F | 23 | | 4 | √ |
| M | 47 | | 2 | |
| F | 49 | | 3 | |
| M | 54 | | 1 | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Full physical household address:

_____

_____

Household Number _23_____

Cluster Number_5_____

Participant ID _____

Since the selected participants should be aged between 18 and 64, the 11-years-old boy, 85-years-old female and 92-years-old male should be excluded.

In the following table, Household #23 which last digit is 3, so it corresponds to Column 3. There are 5 eligible participants in the household, so it corresponds to Row 5. Using Kish Selection Table, the interviewer will select #4 to take the survey, i.e., the 23-years-old female.

**Kish Selection Table**

| Number of Eligible Persons in Household | Last Digit of Household Number | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **0** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** |
| **1** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **2** | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 | 1 | 2 |
| **3** | 3 | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| **4** | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 |
| **5** | 1 | 2 | 3 | 4 | 5 | 1 | 2 | 3 | 4 | 5 |
| **6** | 6 | 1 | 2 | 3 | 4 | 5 | 6 | 1 | 2 | 3 |
| **7** | 5 | 6 | 7 | 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| **8** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 1 | 2 |
| **9** | 8 | 9 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| **10** | 9 | 10 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

# APPENDIX E: Field Test Participant Instructions and Feedback Forms

## Field Test Participant Feedback Instructions

Participants should be allowed to complete the module without interruption as it is timed.

Following completion but before they return their completed modules, the module should be reviewed for questions and responses that the adults found hard to understand or unfamiliar.

The survey should be reviewed section by section as described below.

Thank them for completing the survey and tell them that you would like to discuss their experience of taking it. Please be certain to state at the start that there are no right or wrong answers in this discussion.

Please orient the participants to each section of the module in terms of page and item numbers, and content type. For example,

> **"we will start with the General Health section which goes from page X to page Y. It asks about your general health as well as about specific diagnoses. Next we will look at…"**

Once you're certain they area all looking at the correct section, begin to ask them about any difficulties they might have had with the survey:

1. Were there any words or questions on the survey that were difficult to understand or confusing?
2. Can you tell me which surveys items these were?
3. (For each item) Explain what the item/means and ask what words would be better to use.
4. Were there answers you gave on the survey that were not included as choices (so you completed the 'other' please specify category)?
5. Can you tell me which surveys items these were?
6. Were there things you did not have the information to answer (For example – what is health conditions in your family members, specific lab tests or medicines (prescribed or from traditional healers) for specific health problems?)
7. Can you tell me which surveys items these were?
8. About how many questions did you leave blank? What was the reason you did that?
9. Do you think most adults would find this survey long or just about right?
10. Is there anything else you'd like to tell us about the survey?
11. In order to keep the adults engaged, it is advisable to have one person facilitate the discussion and another person recording their responses on the adult module feedback document.

## Field Test Modules Feedback Document

| ADULT MODULE FEEDBACK DOCUMENT (EXAMPLE)[55] | | COUNTRY/SITE:_____ |
|---|---|---|
| **Sections & Items** | **Feedback from respondents** | **Staff comments** |
| **GENERAL HEALTH (Q1-24)** | | |
| Q1 | | |
| Q2 | | |
| Q3 | | |
| Q4 | | |
| Q5 | | |

[55] For the complete set of Field Test Module Feedback Documents, please contact the CIH Evaluation Team at MATRIX Public Health Solutions, Inc.

# APPENDIX F: Interviewer Comment Sheet

**Site Location (city and country):** _____

Interviewer Name: _____ Date: _____

Survey Module: _____

Administration time

Start time: _____

End Time: _____

***Please ensure that the correct ITEM FORM for the module being field tested is attached to this sheet.***

*Please include all comments in the ITEM FORM as you move with the participant through the module.*

*Specifically, please include all questions asked by the participant during survey administration including items or words that need clarification. Feel free to note if a participant is evidencing difficulty with understanding or completing an item as well. Any comments that may help us to improve the instruments would be helpful. Please detail if the comment is from you the interviewer or the participant.*

*Additional comments may be provided in the space below.*

# APPENDIX G: Data Entry Form

**Site Location (city and country):** _____

**Date:** _____

When data entry is conducted by hand, a 20% quality control check will be expected. From each set of survey instruments, 20% will be randomly selected by a second party and re-entered. The number of discrepant entries will be noted on this form.

***Number of errors:*** _____

***Types of errors (e.g., incorrect number entered, question skipped, question not skipped, etc.)***

_____

_____

_____

***Modules in which errors occurred:***

_____

_____

_____

***Comment:***

# APPENDIX H: Quality Control Report Form

**Site Location (city and country):** _____

**Name of Quality Control Monitor:** _____

**Date:** _____

**Survey Module:** _____

**Venue (circle one):** Neighbourhood School Workplace Health Centre

**Administration time**

**Start time:** _____

**End Time:** _____

***Please follow along with the interviewer script throughout the duration of the interview. Note any deviations from the script. Also note items for which the participant requires additional assistance or has additional questions. As the Quality Control Monitor you are to take notes during the interview without disrupting the interview process. Speak with the interviewer about any issues after you both have left the premises.***

***Please include all comments in the following form.***

**I. Gaining Participation/Eligibility**

__ **Yes the interviewer gained participation**

__ **No, participation was not gained**

**If no, note why (circle one and explain)?**

1. **Interviewer was *unable to locate* household**
2. **There were *no eligible participants* at the household at the time**

   **Was a time obtained for return to household?** _____
3. **The respondent *refused* to be interviewed**

**Explain:** _____

***If #2 (no eligible participants at time) this interview remains pending and the Monitor should attend follow-up.)***

**II. Survey Introduction**

**Does the interviewer appropriately introduce the study. (Circle one.)** **Yes** **No**

**Please comment.**

_____

_____

**Did the interviewer obtain a consent form. (Circle one.)** **Yes** **No**

**III. Survey administration**

Please use the correct item form to look at the items as they are being read to the participant. You will need the item form for the ADULT MODULE.

1. Note if any changes are made to any of the words below each question on the ADULT MODULE item sheet.

2. Comment on the following topics for each item or section as you see necessary.

- Paraphrasing
- Type of clarification: verbatim or rephrasing
- Neutral vs non-verbal communication (e.g. frowning)

**GENERAL COMMENTS**

*Please circle your response and provide an explanation when necessary.*

1. Was the **SPEED** of the interviewer's speech appropriate? **Yes** **No**
   Please explain:

2. Did the interviewer use an appropriate **TONE** throughout the interview? **Yes** **No**
   Please explain:

3. Did the interviewer have appropriate **EYE CONTACT** with the interviewee? **Yes** **No**
   Please explain:

4. Did the interviewer have a **PROFESSIONAL DEMEANOR**? **Yes** **No**
   Please explain:

5. Did the interviewer need to **REFOCUS** the participant? **Yes** **No**
   Please explain:

6. Did the interviewer read the questions **VERBATIM** or did he/she often paraphrase the question?
   **Verbatim** **Paraphrased**
   Please explain:

7. When asked for clarification, did the interviewer typically repeat the question **VERBATIM** or rephrase?
   **Verbatim** **Rephrased**
   Please explain:

8. Did the interviewer typically use **NEUTRAL** or non-verbal communication (e.g., frowning)?
   **Neutral** **Non-verbal**
   Please explain:

9. Was the interviewer friendly? **Yes** **No**

Please explain:

10. Did the interviewer take into account the participant's needs (needing to take a break)? **Yes** **No** **NA**

Please explain:

11. Did the interviewer make encouraging or motivating statement?
**Yes, throughout** **Yes, towards the end** **No**

Please explain:

# APPENDIX I: Adult Hypotheses

## Primary hypotheses

**1. Tobacco**

1.1 Exposure to interventions regarding tobacco use will decrease prevalence of tobacco use as evidenced by the following outcomes:

i) decreasing the number of users

ii) decreasing the average number of tobacco products consumed

[effect modifier: disease status, knowledge, exposure to multiple settings, demographics, advice from health care provider, health service utilisation, depression]

**2. Diet**

2.1 Exposure to interventions regarding food choices will improve food consumption behaviour as evidenced by the following outcomes:

i) increasing the average quantity of fruits and vegetables consumed

ii) increasing the proportion of healthy food preparation methods in the population (e.g., healthier oils, reduction in salt use, healthier cooking methods)

[effect modifier: disease status, exposure to multiple settings, presence of policies, SOC, demographics, health service utilisation, depression]

[mediator: knowledge, SOC]

**3. Physical activity**

3.1 Exposure to interventions regarding moderate to vigorous physical activity will increase physical activity levels as evidenced by the following outcomes:

i) increasing the average number of days with moderate to vigorous physical activity (including leisure-time, transportation-related, or work-related) per week

ii) increasing the average duration of moderate to vigorous leisure physical activity (including leisure-time, transportation-related, or work-related) per week

[effect modifier: disease status, exposure to multiple settings, SOC, presence of policies, demographics, health service utilisation, depression]

[mediator: knowledge, SOC]

## Secondary hypotheses

**4. Tobacco**

4.1 Exposure to interventions regarding tobacco use will decrease prevalence of tobacco use as evidenced by the following outcomes:

i) increasing quit attempts

ii) decreasing the average exposure to secondhand smoke [mediator: knowledge, SOC]

**5. Diet**

5.1 Exposure to interventions regarding food choices will improve food consumption behaviour as evidenced by the following outcomes:

i) decreasing the average quantity of unhealthy foods and drinks consumed

ii) increasing the average number of days per week that healthy foods (other than fruits and vegetables) are consumed

**6. Physical Activity**

6.1 Exposure to interventions regarding moderate to vigorous physical activity will increase physical activity levels as evidenced by the following outcomes:

i) increasing the prevalence of individuals who are engaging in 30 minutes or more for five or more days of physical activity (leisure-time, transportation-related, or work-related) per week

ii) decreasing the average number of hours of sedentary behaviour per week

**7. Dose & Exposure**

Change will vary by dose (number) of intervention sites to which members of the entire family were exposed.

**8. Process Evaluation**

The process by which we obtain the outcomes will vary by site due to differential effects by geo-political factors and community readiness to change (dose, exposure, fidelity).

# APPENDIX J: CIH Indicators Linked to "Core" Adult Surveillance Instruments

## Adult and Clinical Practice Modules

| Indicator | Corresponding Question | |
|---|---|---|
| | **Adult Module** | **Clinical Practice Module** |
| ***Tobacco Indicators*** | | |
| Proportion of the population currently using tobacco | Do you currently smoke any tobacco products, such as cigarettes, cigars, or pipes?<br>Do you currently use any smokeless tobacco such as snuff, chewing tobacco, betel or CSE? | Do you currently smoke any tobacco products, such as cigarettes, cigars, or pipes?<br>Do you currently use any smokeless tobacco such as snuff, chewing tobacco, betel or CSE? |
| Average number of tobacco products consumed per person per day | On average, how many of the following do you smoke each day? (daily users)<br>On average, how many of the following do you smoke per week? (non-daily users)<br>On average, how many times a day do you use the following? (daily users)<br>On average, how many times per week do you use the following? (non-daily users) | On average, how many of the following do you smoke each day? (daily users)<br>On average, how many of the following do you smoke per week? (non-daily users)<br>On average, how many times a day do you use the following? (daily users)<br>On average, how many times per week do you use the following? (non-daily users) |
| Proportion of adult smokers who have made a quit attempt | During the past 12 months, have you stopped smoking tobacco for 24 hours or longer because you were trying to quit? | During the past 12 months, have you stopped smoking tobacco for 24 hours or longer because you were trying to quit? |
| Proportion of the population exposed to secondhand smoke | Did anyone smoke inside any of the following places that you went to in the past 30 days?<br>Your home, a friend's home, your work, a private office building, a school, a health centre, a restaurant, a government building, public transportation | Did anyone smoke inside any of the following places that you went to in the past 30 days?<br>Your home, a friend's home, your work, a private office building, a school, a health centre, a restaurant, a government building, public transportation |
| Average exposure to secondhand smoke (typical day) | In a typical day, for how long are you exposed to other people's smoke? | In a typical day, for how long are you exposed to other people's smoke? |
| Proportion of the population with knowledge | Based on what you know or believe, does smoking tobacco cause the | Based on what you know or believe, does smoking tobacco cause the |

| | | |
|---|---|---|
| of the health effects of tobacco use | following?<br>Stroke; lung cancer; heart attack; cataracts; miscarriage; low birth weight babies<br>How strongly do you agree or disagree with each of the following statements?<br>Cigarettes labeled <low tar> or <light> are less harmful than regular cigarettes; tobacco is addictive | following?<br>Stroke; lung cancer; heart attack; cataracts; miscarriage; low birth weight babies<br>How strongly do you agree or disagree with each of the following statements?<br>Cigarettes labeled <low tar> or <light> are less harmful than regular cigarettes; tobacco is addictive<br>Please read the following statements and indicate your level of agreement by checking the appropriate box.<br>Maternal smoking during pregnancy increases the risk of Sudden Infant Death Syndrome |
| Proportion of the population with knowledge that exposure to tobacco smoke is harmful | Based on what you know or believe, does breathing smoke from other people's cigarettes cause any of the following?<br>Lung cancer in adults; heart disease in adults; lung problems in children; sudden infant death syndrome | Based on what you know or believe, does breathing smoke from other people's cigarettes cause any of the following?<br>Lung cancer in adults; heart disease in adults; lung problems in children; sudden infant death syndrome |
| Proportion of smokers who have been advised to quit smoking by a health care provider | At this facility, did your health care provider do any of the following at any time in the past 12 months?<br>Discuss with you your current smoking status; give you advice or treatment to stop smoking; connect you to a community-based organisation that has programmes to address tobacco cessation | |
| Stages of change for tobacco cessation | Which of the following best describes how you feel about your smoking?<br>Which of the following best describes how you feel about your smokeless tobacco use? | Which of the following best describes how you feel about your smoking?<br>Which of the following best describes how you feel about your smokeless tobacco use? |
| Proportion of the population that is aware of smoke-free policies | Regarding smoking in public areas, do you know of any regulations (restrictions, etc) and how these regulations are enforced/obeyed?<br>Private office buildings; school; HC; restaurants; govt buildings; public transportation<br>[COHORT ONLY] | |
| Proportion of the | How strongly do you agree or disagree | How strongly do you agree or disagree |

| | | |
|---|---|---|
| population that supports smoke-free policies in public places | with smoke-free rules or policies in the following places?<br>Public transportation; at your home (rules); at school; at work; in public outside spaces; in public indoor spaces | with smoke-free rules or policies in the following places?<br>Public transportation; at your home (rules); at school; at work; in public outside spaces; in public indoor spaces<br>Who do you think should be allowed to smoke while in your health centre? |
| Proportion of the population that supports smoke-free policies in workplaces | How strongly do you agree or disagree with smoke-free rules or policies in the following places?<br>At work | How strongly do you agree or disagree with smoke-free rules or policies in the following places?<br>At work |
| Proportion of the population that supports smoke-free policies in schools | How strongly do you agree or disagree with smoke-free rules or policies in the following places?<br>At school | How strongly do you agree or disagree with smoke-free rules or policies in the following places?<br>At school |
| ***Diet Indicators*** | | |
| Quantity of fruits and vegetables consumed: | | |
| *Average number of servings of fruits and vegetables consumed per day* | On the days you eat fruit, on average how many servings of fruit do you eat?<br>On the days you eat vegetables, on average how many servings of vegetables do you eat? | On the days you eat fruit, on average how many servings of fruit do you eat?<br>On the days you eat vegetables, on average how many servings of vegetables do you eat? |
| *Proportion of the population consuming 5 or more servings of fruits and vegetables per day* | How many days per week do you usually eat or drink each of the following items?<br>On the days you eat fruit, on average how many servings of fruit do you eat?<br>On the days you eat vegetables, on average how many servings of vegetables do you eat? | How many days per week do you usually eat or drink each of the following items?<br>On the days you eat fruit, on average how many servings of fruit do you eat?<br>On the days you eat vegetables, on average how many servings of vegetables do you eat? |
| Proportion of the population that uses healthy food preparation methods, particularly: | | |
| *Healthier oils*[56] | How often do you use the following types of oils or fats for meal preparation in your household? | |
| *Reduced salt use* | Do you usually add salt <and/or CSE> to the food during meal preparation and/or cooking? | |

[56] Healthy oils are those low in saturated and trans-saturated fats and high in unsaturated (both mono-unsaturated and poly-unsaturated) fats. Vegetable oils are, on average, healthier than animal-based oils.

| | | |
|---|---|---|
| | Do you add salt <and/or CSE> to your food after it has been cooked or when it is served at the table? | |
| *Healthier cooking methods*[57] | During the past 7 days, how often did you use the following food preparation methods?<br>Frying or deep-frying; stir frying; steaming/boiling/braising; baking; roasting, grilling, or broiling<br>When eating at home, how often is the food you eat fried? | |
| Frequency of unhealthy foods and drinks consumed, particularly: | | |
| *Average number of days that sugar/sweets are consumed per week* | How many days per week do you usually eat or drink each of the following items? | How many days per week do you usually eat or drink each of the following items? |
| *Average number of days that sugar-sweetened beverages are consumed per week* | How many days per week do you usually eat or drink each of the following items? | How many days per week do you usually eat or drink each of the following items? |
| *Average number of days that salt and/or salty foods are consumed per week* | How many days per week do you usually eat or drink each of the following items?<br>Do you add salt <and/or CSE> to your food after it has been cooked or when it is served at the table? | How many days per week do you usually eat or drink each of the following items? |
| *Average number of days that high-fat foods are consumed per week* | How many days per week do you usually eat or drink each of the following items?<br>When eating at home, how often is the food you eat fried?<br>When eating out, how often is the food you eat fried? | How many days per week do you usually eat or drink each of the following items? |
| Frequency of healthy foods (other than fruits and vegetables) consumed | | |
| *Average number of days that legumes, whole grains, and nuts are consumed per week* | How many days per week do you usually eat or drink each of the following items? | How many days per week do you usually eat or drink each of the following items? |

[57] Healthier cooking methods include: boiling, baking, grilling, steaming, stir-frying with healthy oils, etc. (Deep-frying is considered unhealthier)

| | | |
|---|---|---|
| Proportion of the population with knowledge of the benefits of healthy eating | Do you believe what you eat or drink can make a difference in your chances of getting the following conditions?<br>Heart disease, diabetes, cancer | Please read the following statements and indicate your level of agreement by checking the appropriate box.<br>A diet high in saturated fat and red meat increases the risk of cardiovascular disease |
| Proportion of the population with knowledge of the composition of a healthy diet | How important do you think each of the following is for one's health?<br>Eating more fibre, eating more F&V, eating less sugar, eating less fat, eating/using less salt, changing cooking methods | |
| Stages of change for increase in consumption of fruits and vegetables | Do you currently eat 5 or more servings of fruits and vegetables a day? | |
| Stages of change for reduction in consumption of high-fat, high-salt, high-sugar foods | Do you currently avoid eating high-fat, high-salt, and/or high-sugar foods? | |
| Proportion of the population who have been advised/encouraged by a health care provider to eat healthily | At this facility, did your health care provider do any of the following at any time in the past 12 months?<br>Discuss with you your current diet; give you advice about how to follow a healthy diet; connect you to a community-based organization that has programmes to address diet, physical activity, and/or tobacco cessation? | |
| Proportion of the population that reads food labels | In the past 30 days, which of the following statements best describes your reaction to the nutrition labels on food items? | |
| ***Physical Activity Indicators*** | | |
| Average number of days with moderate to vigorous physical activity per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>During the past 7 days, on how many days did you do moderate physical activities? | During the past 7 days, on how many days did you do vigorous physical activities?<br>During the past 7 days, on how many days did you do moderate physical activities? |
| Average duration of moderate to vigorous physical activity per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one |

| | | |
|---|---|---|
| | of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days? | of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days? |
| Average number of days with at least 30 minutes of physical activity per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? |
| Average duration of physical activity per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? |
| Proportion of the population who engage in physical activity for 30 minutes or more for 5 or more days per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one |

| | | |
|---|---|---|
| | of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days?<br>Do you currently do 30 minutes or more of physical activity 5 days a week? | of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days?<br>Do you currently do 30 minutes or more of physical activity 5 days a week? |
| Proportion of the population who engage in physical activity for 60 minutes or more for 5 or more days per week | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? | During the past 7 days, on how many days did you do vigorous physical activities?<br>How much time did you usually spend doing vigorous physical activities on one of those days?<br>During the past 7 days, on how many days did you do moderate physical activities?<br>How much time did you usually spend doing moderate physical activities on one of those days?<br>During the past 7 days, on how many days did you walk for at least 10 minutes at a time?<br>How much time did you usually spend walking on one of those days? |
| Average number of hours of sedentary behaviour per day | During the last 7 days, how much time did you usually spend sitting on a weekday? | During the last 7 days, how much time did you usually spend sitting on a weekday? |
| Proportion of the population with knowledge of the health benefits of physical activity | How much do you agree or disagree with each of the following statements? If you participate in regular physical activity or sports for 30 minutes or more, 5 days a week, then you….<br>Will feel less depressed and/or bored; will lose weight; will feel less tension and stress; will improve your health or reduce your risk of disease; will do better on your job; will improve your heart and lung fitness; will gain muscle | Please read the following statements and indicate your level of agreement by checking the appropriate box.<br>Physical inactivity can lead to a decrease in energy levels<br>Physical inactivity can lead to a decrease in cardio-respiratory functions. |

| | | |
|---|---|---|
| Stages of change for increasing physical activity | Do you currently do 30 minutes or more of physical activity 5 days a week? | |
| Stages of change for reducing sedentary behaviour | Are you currently working to reduce your sedentary activities (screen time and other sitting activities) each day outside of work? | |
| Proportion of the population advised by a health care provider to be physically active | At this facility, did you health care provider do any of the following at any time in the past 12 months?<br>Discuss with you your current level of physical activity; give you advice or treatment to increase physical activity; connect you to a community-based organization that has programmes to address diet, physical activity, and/or tobacco cessation? | |
| Average number of days of active transport per week | During the past 7 days, on how many days did you walk or ride a bicycle at least part of the way to and from work? | During the past 7 days, on how many days did you walk or ride a bicycle at least part of the way to and from work? |
| ***Alcohol Use Indicators*** | | |
| Proportion of the population consuming alcohol | In the past month (30 days), how frequently have you had at least one drink of alcohol (such as beer, wine, spirits, fermented cider or CSE)?<br>When you drink alcohol, on average, how many drinks do you have during one day? | |
| ***General Health Indicators*** | | |
| Disease status | | |
| *General* | How would you assess your present state of health? | |
| *Obesity* | How tall are you without your shoes on?<br>How much do you weigh without your shoes on? | |
| *Cardiovascular disease* | Have you ever been diagnosed as having or been treated for heart disease, heart attack, or stroke? | |
| *Diabetes or pre-diabetes* | Have you ever been diagnosed as having or been treated for diabetes?<br>Have you ever been diagnosed as having or been treated for raised blood | |

| | | |
|---|---|---|
| | glucose or pre-diabetes (including during an illness or pregnancy)? | |
| *Hypertension* | Have you ever been diagnosed as having or been treated for high blood pressure? | |
| *Hypercholesterolemia* | Have you ever been diagnosed as having or been treated for high cholesterol? | |
| *Cancer (lung, mouth, esophageal)* | Have you ever been diagnosed as having or been treated for cancer (lung, mouth, esophageal)? | |
| *Cancer (breast, stomach, colorectal)* | Have you ever been diagnosed as having or been treated for cancer (breast, stomach, colorectal)? | |
| *Family Risk* | Who in your family, other than yourself, has been diagnosed as having or been treated for the following conditions? [options are spouse, child, parent, sibling, grandparents, aunts/uncles, cousins (does not include those related to you by marriage)]<br>High blood pressure; high cholesterol; heart disease, heart attack, or stroke; diabetes; clinical obesity; cancer (breast, stomach, colorectal); cancer (lung, mouth, esoph) | |
| Depression | During the last month, have you often been bothered by feeling down, depressed, or hopeless?<br>During the last month, have you often been bothered by little interest or pleasure in doing things? | |
| Stress | Have you been feeling tense, stressed or under a lot of pressure during the past month (30 days)? | |
| Health service utilisation | Are you currently covered under any <health insurance>?<br>What are the barriers to receiving health care?<br>Which type of health care provider did you see in the past 12 months for health care advice or treatment?<br>What kind of facility do you usually go to for your routine healthcare? | Which of the following health care facilities do you usually go to for your routine health care? |

| | | |
|---|---|---|
| | Have you visited this health care facility in the past 12 months? | |
| Biometric measures | | |
| *BMI* | How tall are you without your shoes on?<br>How much do you weigh without your shoes on? | |
| *Biometric measures taken in Cohort and WP (Blood pressure, hip/waist ratio, cholesterol (total, LDL, HDL), triglycerides, fasting glucose, skin fold)* | Measurements taken in Cohort and Workplace (industry) sample | |
| ***Demographics*** | | |
| Age | How old are you? | How old are you? |
| Sex | Sex | Sex |
| Ethnicity/race | What is your <ethnic/racial/cultural> background? | What is your <ethnic/racial/cultural> background? |
| Marital status | What is your marital status? | |
| Household occupants | How many children under the age of 18 are living in your household?<br>How many adults 18 and older (including yourself) are living in your household? | |
| Education level | What is the highest level of education you have completed? | |
| Work status | Which of the following best describes your work?<br>Which of the following best describes your work status during the past 30 days? | |
| Ability to buy/afford food | During the past 30 days, was there any time that you and/or your family did not have food or money to buy food? | |
| Housing status | Which of the following best describes the place in which you live? | |
| Household assets | Does your household have the following items? | |

| ***Exposure to multiple settings*** | | |
|---|---|---|
| At home/in community | To be assessed using colour-coded surveys or GPS for home interviews | To be determined through Q53 (country-specific question due to diversity of countries and settings) |
| At work | Do you work at any of the following places? | To be determined through participant ID code |
| At health care centre | Which of the following health care facilities do you usually go to for your routine health care?<br>Have you visited this health care facility in the past 12 months? | Which of the following health care facilities do you usually go to for your routine health care? |
| Number of family members exposed to number of intervention settings | To be assessed in follow-up surveys | To be assessed in follow-up surveys |